TEKNILLINEN TIEDEKUNTA

9Solutions Product Quality System

Aleksi Lakkala

PROCESS ENGINEERING

Master’s thesis

April 2020

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Supervisors: Harri Haapasalo, Erno Mustonen

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ABSTRACT
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Abstract

Quality management (QM) is an important managerial tool in production and service environments. It covers the social and technical factors affecting quality of products and services within an organization. Global competition and increasing customer demands emphasize the importance of QM in different organizations. If applied correctly, QM can be a success factor for a company, by increasing customer satisfaction and profitability of the company.

The thesis is a constructive research in nature and performed in a case company. The objective of the study is to examine the current state and the biggest challenges regarding QM in the case company and to suggest improvement proposals based on theory and empirical findings. The study addresses QM and its utilization in the case company in the form of a quality management system (QMS). The literature review familiarizes with the concept of quality the QM principles, and its involvement in company's functions, such as product development (PD). The empirical part of the research examines the current state of QM at the case company with the use of theme interviews. Also, three benchmarking interviews contribute to empirical study, highlighting the best QM practices from technology companies of similar magnitude.

The empirical part of the study demonstrates that in the case company quality is managed with several procedures, but systematic and documented system, as well as clear, strategy-based quality policies and objectives, are missing. The lack of systematic QM complicates detecting problems in PD and other organizational functions, leading to both direct and indirect quality costs. Thus, the existing literature's perception of reactive QM applies to the case company for the most part. The study aims to solve QM related challenges in the company by utilizing the key points of existing literature and benchmarking observations. Existing literature emphasizes the concepts of quality planning and continuous improvement as the most important factors for an organization to move towards preventive QM, including planning for the quality management system. The QMSs of the benchmarking companies differ, but their unifying factors were observed to be process management, clear documentation of the system, clear objectives, and systematic QM in PD processes. Evaluating the theory and empirical findings demonstrates, that QM at the case company can also be developed with the implementation of a process-based QMS.

The proposed improvement model covers those basic QM methods, that the case company should assimilate to develop a QMS. The development proposals include quality planning, measuring organizational performance and process management, which together create a body for the QMS. Also, recommendations for QMS documentation procedures and audits are presented. Together, the improvement proposals offer the case company a concrete model for initiating quality work and developing the quality of products and services.

Additional Information

Key words: quality, quality management, quality management system, quality planning, process management

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Tiivistelmä

Laadunhallinta on tärkeä johtamisen apuväline sekä tuotanto- että palveluympäristöissä. Se kattaa ne organisaation sosiaaliset ja tekniset tekijät, jotka vaikuttavat tuotteiden ja palveluiden laatuun. Nykyinen globaali kilpailu ja asiakkaiden kasvavat laatuvaatimukset korostavat laadunhallinnan tarvetta erilaisissa organisaatioissa. Oikein sovellettuna laadunhallinta voi olla menestystekijä yritykselle, parantaen asiakastyytyväisyyttä ja yrityksen kannattavuutta.

Tämä diplomityö on luonteeltaan konstruktiivinen tutkimus, joka suoritettiin kohdeyrityksessä. Työn tavoitteena on selvittää kohdeyrityksen laadunhallinnan nykytila ja suurimmat haasteet, sekä esittää kehitysehdotuksia kirjallisuuden ja empiiristen havaintojen pohjalta. Tutkimus käsittelee laadunhallintaa ja sen hyödyntämistä kohdeyrityksessä laatujärjestelmän muodossa. Kirjallisuuskatsaus perehtyy laadun käsitteeseen, laadunhallinnan periaatteisiin sekä sen merkitykseen yrityksen funktioille, kuten tuotekehitykselle. Empiirinen osa tutkimuksesta tutkii laadunhallinnan nykytilaa kohdeyrityksessä teemahaastattelujen avulla. Myös kolme benchmarking-haastattelua ovat osana empiiristä tutkimusta, tuoden esiin parhaita laadunhallinnallisia käytäntöjä vastaavan kokoluokan teknologiayrityksistä.

Tutkimuksen empiirinen osa osoittaa, että laatua hallitaan kohdeyrityksessä eri toimintamallien avulla, mutta järjestelmällinen ja dokumentoitu laatujärjestelmä sekä selkeät, yrityksen strategiaan perustuvat laatulinjaukset ja -tavoitteet puuttuvat. Systemaattisen laadunhallinnan puute vaikeuttaa ongelmien havaitsemista niin tuotekehityksessä kuin muissakin organisaation toiminnoissa, johtaen sekä suoriin että epäsuoriin laatukustannuksiin. Täten kirjallisuuden käsitys reaktiivisesta laadunhallinnasta pätee suurin osin myös kohdeyrityksessä. Tutkimus pyrkii ratkaisemaan laadunhallinnallisia haasteita yrityksessä hyödyntämällä olemassa olevan kirjallisuuden pääkohtia sekä havaintoja benchmarkingista. Olemassa oleva kirjallisuus korostaa laatusuunnittelun ja jatkuvan kehittymisen konsepteja tärkeimpinä tekijöinä organisaation kehittyessä ennakoivaan laadunhallintaan, sisältäen myös laatujärjestelmän suunnittelun. Benchmarking-yritysten käyttämät laatujärjestelmät poikkeavat toisistaan, mutta niiden yhdistävinä, laatua edistävinä tekijöinä havaittiin prosessijohtaminen, selkeä järjestelmädokumentaatio, selkeät tavoitteet sekä järjestelmällinen laadunhallinta tuotekehitysprosesseissa. Kirjallisuuden ja empiiristen havaintojen vertailu osoittaa, että myös kohdeyrityksen laadunhallintaa voidaan kehittää prosessipohjaisen laatujärjestelmän toteuttamisen avulla.

Ehdotettu kehitysmalli kattaa ne perustavanlaatuiset laadunhallinnan menetelmät, jotka kohdeyrityksen tulee sisäistää laatujärjestelmän kehittämiseksi. Kehitysehdotukset sisältävät laatusuunnittelun, organisaation suorituskyvyn mittaamisen ja prosessijohtamisen, jotka yhdessä luovat rungon laatujärjestelmälle. Myös suositukset laatujärjestelmän dokumentaatiomenetelmistä ja auditoinnista on esitetty. Yhdessä kehitysehdotukset tarjoavat kohdeyritykselle konkreettisen mallin laatutyön aloittamiseksi, sekä tuotteiden ja palveluiden laadun kehittämiseksi.

Muita tietoja

Avainsanat: laatu, laadunhallinta, laatujärjestelmä, laatusuunnittelu, prosessijohtaminen

PREFACE

Writing this master's thesis been a remarkable journey, culminating many years of studies at the university. The main objective of the study was to construct an improvement framework for a quality management system at the case company. The research process has demonstrated the importance of perseverance and good planning for constructing valid results. The study has strengthened my knowledge in quality management and its implementation in different organizations. Overall, the research process has been a remarkable learning experience, creating a solid foundation for my future career.

Foremost, I would like to thank 9Solutions for providing interesting topic for the study and for letting me get acquainted with the organization. Thank you, Ville Isoherranen and Teemu Sivonen from 9Solutions, for looking after my work and providing necessary information for the study. I would also like to thank the benchmarking companies and their representatives for participating in the research process. From the University of Oulu, I would like to thank my supervisors Professor Harri Haapasalo and Researcher Erno Mustonen for your feedback and advice. Lastly, big thanks to my family, friends, and girlfriend. Your support and guidance have been invaluable during my studies and will help me navigate future challenges with confidence.

Oulu, 5.5.2020 Aleksi Lakkala

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APPENDICES

ABBREVIATIONS

BOM	Bill of materials
BSC	Balanced scorecard
CoQ	Costs of quality
CI	Continuous improvement
ISO	International Organization for Standardization
KPI	Key performance indicator
PD	Product development
PDM	Product data management
QA	Quality assurance
QC	Quality control
QM	Quality management
QMS	Quality management system
RMA	Return merchandise authorization
SME	Small and medium-sized enterprise
SPI	Software process improvement
SQA	Software quality assurance
SQC	Software quality control
SQP	Software quality planning
SQM	Software quality management

1 INTRODUCTION

1.1 Study background

In today's global and competitive market environment, constantly increasing quality requirements of customers and the increasing supply of competitively priced products and services from low labour cost countries can hinder company's ability to compete in the marketplace. To face these emerged challenges and to maintain a competitive edge over their competitors, quality management (QM) and continuous improvement have been utilized in companies to provide better product, service, and process quality to satisfy the ever-increasing demands of the marketplace. (Dale et al. 2009) Therefore, good quality performance is a necessity to successfully compete in the global marketplace of the twenty-first century. Several improvement approaches to quality has been adopted to respond to the market pressure, such as quality management system (QMS) standards, business process re-engineering (BPR), Lean thinking, Six Sigma, statistical process control (SPC) and total quality management (TQM). (Oakland 2014)

QM influences companies' financial performance, as the quality-related costs usually range from 5 to 25 % of annual sales turnover, depending on the industry and the way quality is managed in the company (Dale et al. 2009). Top management should recognize quality's influence on company's financial performance, encouraging to start quality improvement projects (Cheah et al. 2011). Quality improvement can lead to a chain-reaction of benefits in companies. For example, as described by quality guru Dr. W. E. Deming, successful quality improvement project for cost reduction will also improve productivity, reduce prices and thus increase the company's market share, which lead to long term presence of the company and growth. (Carrión-García & Grisales 2015)

In modern view, quality is achieved through process improvement and process management. These principles are widely accepted and recognized in QMS standards. Improving business processes and supporting process management infrastructure are therefore seen crucial for product and service quality improvement. (Nanda 2005) A

QMS should apply to and interact with this process management infrastructure, so that quality objectives can be accomplished, and customer requirements are met. The system should consist of an assembly of components, such as management responsibilities, resources, and processes, with a focus on customer satisfaction and continuous improvement. (Oakland 2014)

1.2 Research scope and objectives

This study's primary focus is on QM and how it should be approached in companies. The importance of quality management has also been noticed in the case company, where quality, and sometimes the lack of it, is recognized on many areas of firms' operation. This thesis focuses on improving case company's product quality by proposing a framework for quality management system. The case company is the market leader in its field in Finland and offers tailored solutions in business-to-business (B2B) environment. The company's offering consists of hardware, software, and service aspects, and often the developed solutions include all three aspects in them.

The main objective of this study is to examine the current state and challenges of quality management at the case company. The primary research objective can be approached through three research questions, described below.

RQ1: What are the key elements and best practices of systematic quality management, especially in small and medium-sized enterprises, according to earlier research?

RQ2: What are the current practices and challenges for managing quality in the case company and the benchmarking companies?

RQ3: How the case company should improve its quality management practices for increased product quality?

The case company's current state is analysed based on the key findings of existing literature. As a result, a framework is developed for a QMS and its implementation at the case company, based on literature and empirical findings. The improvement

proposals address the challenges found in the case company, by utilizing theory concepts and best practices from benchmarking surveys.

1.3 Research process

The research process is presented in figure 1. In the beginning of the research process, the scope of the thesis was defined during a few meetings with the responsible personnel from the company. After the research scope was defined, a literature review was conducted to enhance understanding of the topic and to create foundation for the rest of the research. The literature review, presented in chapter 2, answers the first research question. It examines earlier research and current literature related to quality in general, quality management and its role in product development and productization. Based on the literature review, an interview questionnaire was created.

The current state analysis was conducted through collecting data in the case company and three benchmarking companies. Internal interviews were held in the case company to understand the current state of the case company, and external interviews were to study the best practices of managing product quality in similar sized tech companies. Based on gathered material, the current methods, practices and challenges present in the case company and benchmarking companies were analysed according to the literature findings. Together, the interviews provide answer to the second research question. The current state analysis, including the benchmarking interviews, is presented in chapter 3. The empirical research findings together with theoretical framework contribute to the main goal of the study, finding improvement opportunities and creating improvement framework to improve quality management in the case company. The improvement proposals and implementation plan are presented in chapter 4.

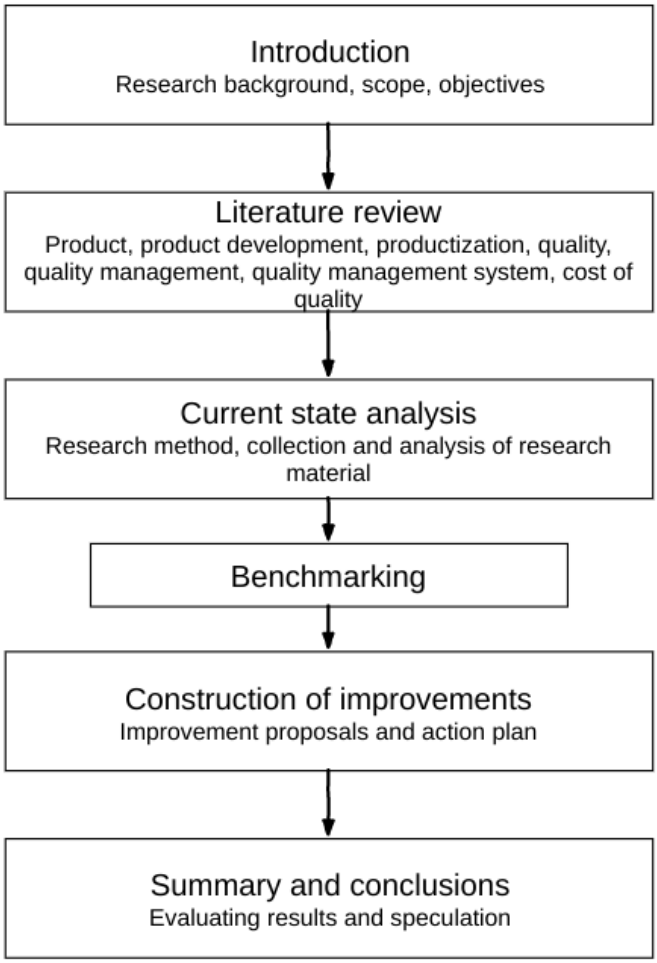

Figure 1: The phases of the research process

2 LITERATURE REVIEW

2.1 Fundamentals of quality management

2.1.1 Quality

Quality has different definitions in today's business world. To use the word quality correctly, the person and his audience must share a common understanding of the meaning behind it. The same principle of common understanding applies to an organization's view of quality, ensuring that everyone in each of the departments are focused on the same objectives. (Dale et al. 2009) One way to view quality is as a continuous improvement process of products and services, that focuses on customer satisfaction (Wang et al. 1995).

ISO 9000:2015 standard defines quality as "degree to which a set of inherent characteristics of an object fulfils requirements" (ISO 2015). Montgomery (2009) states the traditional view of quality as "Quality means fitness for use", which can be divided into two general aspects: "Quality of design" and "quality of conformance." Quality of design describes the intentional levels of quality of the product and quality of conformance on the other hand, describes how the product matches the specifications required by the design. (Montgomery 2009) Dale et al. (2009) also includes abilities and field services under the fitness for use definition. The principle of fitness for use is to prevent over-specifying products or services. In the end, the fit for use of a product or service is judged by the customer. (Dale et al. 2009) Broadly categorized, quality definitions of experts fall into two categories, "satisfying applicable specifications" and "satisfying customers" (Nanda 2005).

A modern definition of quality is "Quality is inversely proportional to variability." Simply put, the quality of the product increases, as variability in product's important features decreases. Thus, "quality improvement is the reduction of variability in processes and products." If process performance variability is too excessive, the amount of wasted money, time and effort is increased due to increased scrap, repairs and maintenance work. Therefore, improving product quality is also reduction of waste.

Product quality can be defined through eight key points: performance, reliability, durability, serviceability, aesthetics, features, perceived quality, and conformance to standards. Thus, quality can be considered an entity with many features. (Montgomery 2009) From technical standpoint, quality has two established meanings; "a characteristics of a product or service that bears on its ability to satisfy stated or implied needs" and "a product or service free of deficiencies" (Nanda 2005).

For today's global competition, quality has become one of the most important drivers. Global competition intensifies and demand for better quality products by customers have made companies realize that high quality is one of the main requirements for a product or a service to successfully compete in the marketplace. (Demirbag et al. 2006) Quality is seen as the most important competitive weapon for a company to build and enjoy reputation. On the other hand, reputation for poor quality is long lasting and can become national or international. (Oakland 2014) Quality is currently one of the most important decision factors for customers (Montgomery 2009). Therefore, quality is seen as an essential factor for both small and large manufacturing and service organizations. (Hoyer & Hoyer 2001)

2.1.2 Quality management

Broadly, QM is an approach to management, consisting of set of mutually reinforcing principles, that are supported by practices and techniques (Dean & Bowen 1994). Traditional quality management revolved around routine tasks and detecting problems through inspection activities. Today, the QM focus is shifted towards preventing problems, managing future risks, and improving customer satisfaction through reducing variation within an organization and applying supply chain-wide co-operation. (Dale et al. 2009) The seven quality management principles in BS EN ISO 9000 (2015) are defined as:

1. Customer focus
2. Leadership
3. Engagement of people
4. Process approach
5. Improvement

6. Evidence-based decision making
7. Relationship management

These seven principles are used as foundation to guide performance improvement of an organization and form the basis for ISO 9000 QMS standard series. The principles are not in priority order and their relative importance ways of applying them can vary between different organizations. (ISO 2015)

QM has been evolving throughout the years. The development levels include inspection, quality control, quality assurance and total quality management (TQM). During the last decades, quality management systems have changed in a sense that quality control has been replacing or been added to reinforce inspection activities, and quality assurance has been developed. Today, many companies are working towards TQM via the use of company-wide process of continuous improvement. The levels of quality management evolution and characteristics of each maturity level are illustrated in figure 2. (Dale et al. 2009)

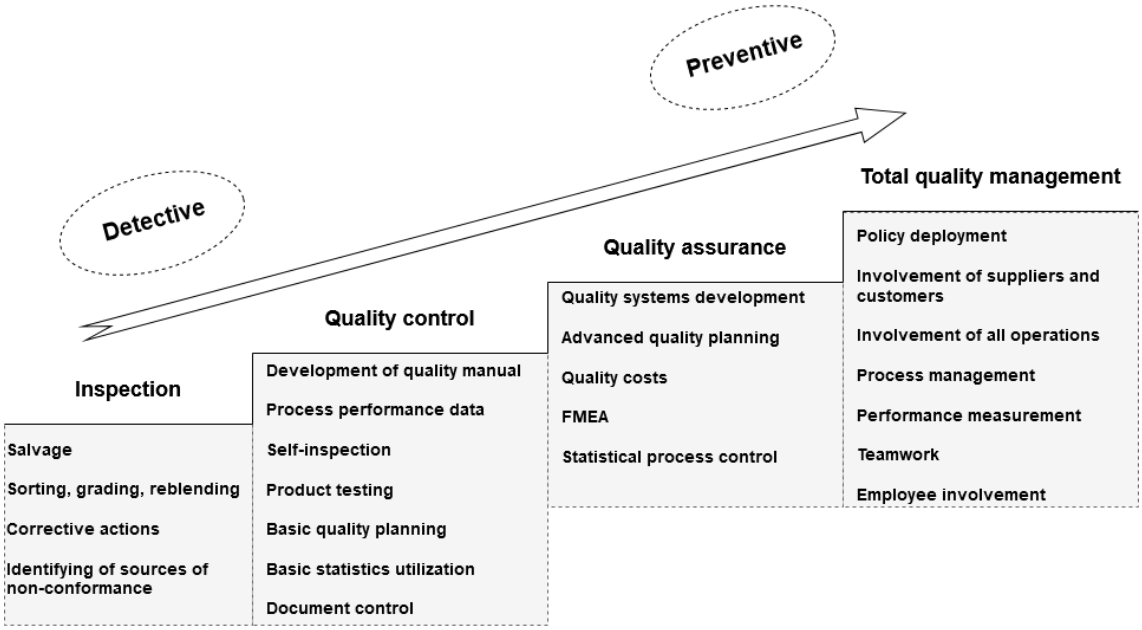

Figure 2. The levels of QM evolution and elements (adapted from Dale et al. 2009).

QM influences firm's internal environment and relationship with its external environment, focusing on technical and social parts of an organization (Molina et al. 2007). QM is recognized as a strategic tool to improve processes, access foreign markets and increase competitiveness (Janis 2012). QM includes all activities within an organization, that are required to plan for quality and all activities that are required to satisfy quality objectives. QM can be seen to comprise four main elements: quality planning, quality control, quality assurance and quality improvement, which are presented in figure 3. Each of these elements are described more closely in this chapter. (Nanda 2005)

Figure 3. The four main elements of QM (adapted from Nanda 2005)

Quality planning

Quality planning is a strategic activity that affects organization's long-term business success. If top-level quality plan is missing, organization wastes a large amount of time, money, and effort, as it must deal with faulty designs, manufacturing defects, field failures and complaints from customers. Identifying internal and external customers and their needs (voice of customer, VOC) is crucial to perform quality planning, so that products or services can be developed to meet or exceed customer expectations. (Montgomery 2009)

Establishing both short- and long-term quality improvement objectives demonstrates management vision and strategic quality thinking. Achieving longer term quality

objectives may be planned incrementally so that there is continual improvement toward the set objective. The long-term objective can be split into several smaller quality objectives that can be met in smaller short-term increments. A short-term quality objective is applicable to a product development project or over a period of few months. (Nanda 2005)

Quality planning includes identification of quality requirements for both processes and products. Process quality requirements can be usually seen as requirements set for the QMS and product requirements apply to specific product or family of products and are quantitative or qualitative in nature. Qualitative product requirements can be related to user-friendliness and quantitative requirements can be related to reliability of the product, for example. (Nanda 2005) On the QM evolution scale, presented earlier in this chapter, quality planning is present from quality control to total quality management. In quality control, basic quality planning is present. As the organization develops quality assurance functions, advanced quality planning is introduced. Top management is required to change the organizational policy from detection to prevention in order to introduce quality planning and continuous improvement to various departments. (Dale et al. 2009)

Quality planning also includes planning for a QMS. Nanda (2005) summarizes key elements for planning a QMS in a product development company:

- Establishment of product development and support processes
- Establishment of control points (milestones) and associated entry and exit criteria
- Definition of methods
- Establishment of workmanship standards
- Identification of required resources
- Identification of work products (intermediate work products included)
- Establishment of guidelines for tailoring of product development processes. For example, in the context of a single product development project.

Quality control

Juran (1998) defines quality control (QC) as a universal managerial process to conduct operations so that process stability is provided, and adverse change is prevented. The stability of process is maintained by evaluating performance, comparing performance to targets, and acting on the difference. (Juran 1998) Quality control measures provide greater process control and lower rate of non-conformances, compared to a bare screening inspection-based operation, even though inspection may still be the main tool for preventing faulty products. (Dale et al. 2009)

A system of quality control provides a way to find product related information, such as product and performance specifications in detail, raw materials, a system to control product related paperwork and procedures, intermediate-state product-testing and reporting activities, process performance data logs and process information feedback to suppliers and specified personnel. (Dale et al. 2009) Montgomery (2009) states, that variability leads to low quality, therefore statistical techniques, such as statistical process control (SPC) and designed experiments are considered tools of QC and quality improvement. (Montgomery 2009)

Companies, whose QM is based on inspection and QC are considered operating in a detection-type mode, that focuses on removing the negative things after they have occurred. This method leads to relying on quick fixes as the only option, as defects are discovered late in the process. (Dale et al. 2009) Typical QC process flow is illustrated in figure 4. Activities include the executed process, verification of the process output by comparing it with applicable specifications, standards or requirements and corrective actions if the output does not meet the requirements. The corrective actions are made, and the process execution and verification are repeated until the process is in control. (Nanda 2005)

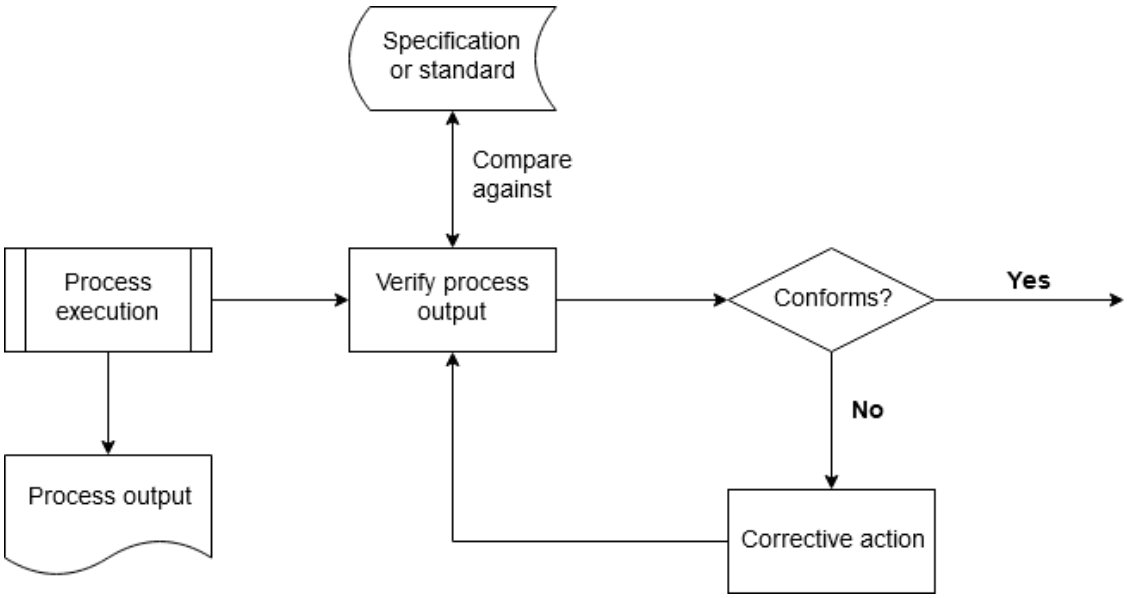

Figure 4. Process flow of generic QC system (adapted from Nanda 2005)

Detective quality control includes operations such as after-the-event inspecting, checking, testing, troubleshooting and other methods related to "quick fixing" the problem. Therefore, quality is not improved, only seen when it is missing. It may also lead to a way of thinking that current rate of inspection is not high enough, and to blaming of operators as the only cause for non-conformity of products instead of the system itself. Inspection and quality control-based quality system may prevent faulty products but does not prevent them being made in the first place. The whole take on quality involves a backward-looking mentality, extra efforts spent on rework and retesting, and ultimately leading in a decrease of bottom-line profit. Detection type environment may also affect the overall climate at work negatively, as organization is occupied by surviving in the business instead of making improvements. (Dale et al. 2009). Asking the right questions, such as "Are we capable of doing the job correctly?" and "Do we continue to do the job correctly?" in the right order can help to replace a detective strategy with a preventive one (Oakland 2014).

Quality assurance

The primary purpose of quality assurance is to verify that control is being maintained in the system and its processes (Juran 1998). As most of the quality related issues originate from inadequate design of products or processes, achieving a lasting and continuous improvement of quality requires focusing efforts on planning and preventing problems at the source, instead of detection of non-conformances. Compared to quality control system, quality assurance system provides uniformity and conformity and the use of "the seven quality control tools", that include: check sheets, histograms, pareto analysis, graphs, statistical process control tools, failure mode and effect analysis (FMEA) and realized quality costs. (Dale et al. 2009)

With QA, emphasis is shifted towards continuous improvement and problem prevention by training and involving personnel, focusing further on quality planning and product design and cross-functional problem solving. With the use of quality assurance tools, the system has most likely achieved the requirements of the ISO 9001 standard. (Dale et al. 2009) Quality assurance prevents quality problems through planned and systematic activities, including the establishment of a quality management system and ensuring its adequacy, auditing the operation of the system and reviewing the system (Oakland 2014). The main principle of a prevention-based QMS is presented in figure 5.

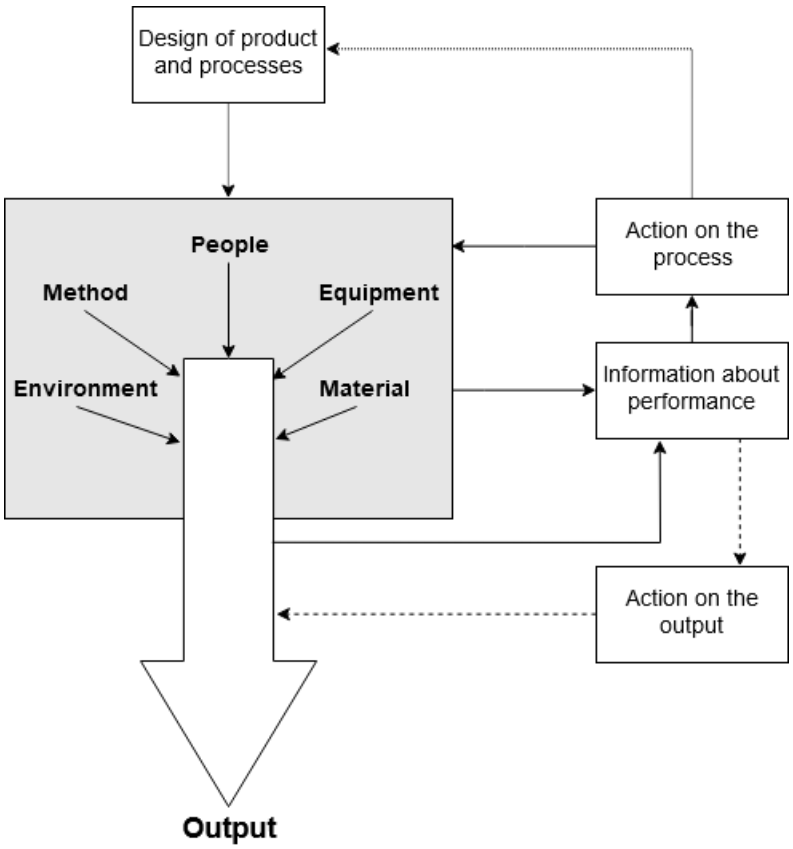

Figure 5. A prevention-based quality system (adapted from Ford Motor Company 1985)

The key to successful quality assurance model, according to Montgomery (2009), is documentation of quality system. Related quality documentation involves four main components: policy, procedures, work instructions and specifications, and records. The policy component states what is to be done and why, while procedures have focus on the methods and related personnel that implements the policy. Records include documentation of policies, procedures, and work-related instructions. Having records also allows tracking of products or product batches, helping with customer complaints, product recalls and assessing corrective actions (Montgomery 2009).

A quality assurance system is considered a preventive system, improving quality of products and services. On top of increased quality of services and products, a preventive system improves productivity, as product, service and process design are at the core of operation. The practical benefits of a preventive system include identification of defects early in the process and prevents the production of non-conforming items. For an

organization to move from detection-based system to prevention-based system, a chance in management style and way of thinking is required to develop a new operating philosophy and approach. (Dale et al. 2009)

Quality improvement

Quality improvement benefits the organization by effecting on both efficiency and effectiveness of its operation. Increasing efficiency relates to savings in time, money, and effort expended to accomplish a task. Effectiveness on the other hand describes the goodness or quality of an accomplished task. Good quality improvement solutions provide a balance between efficiency and effectiveness. Therefore, quality improvement can be defined as enhancement in the effectiveness and efficiency in processes and enhancement of products ability to satisfy applicable requirements. Both aspects enhance the organization's ability to meet customer expectations, which is translated into improved customer satisfaction. (Nanda 2005) Better quality is considered a beneficial change and positively affects two quality aspects of products (Juran 1998):

- **Product features** – increases customer satisfaction, income oriented
- **Freedom from deficiencies** – creates customer dissatisfaction and chronic waste, cost oriented

Quality improvement on income-oriented aspects may include actions such as: creation of new features in product development to increase customer satisfaction, or business process improvement to reduce the cycle time that leads to better service to customers. Actions to reduce deficiencies may consist of increasing yield of factory processes, reduction of the error rates in offices and field failure reduction. Quality planning is crucial activity in both quality improvement contexts. For activities focused on increasing income, a quality planning roadmap is utilized, consisting of identified customers, needs of the customers and means to develop the product features according to the needs. For chronic waste reduction, the quality improvement focuses on discovering the causes of some products meeting the goal and some not and applying means to remove those negative causes. (Juran 1998)

Quality guru Dr. W. E. Deming explains the positive effect of quality improvement in different organizational activities and performance. Deming's chain reaction, presented in figure 9, demonstrates the benefits of quality improvement within an organization. (Carrión-García & Grisales 2015)

Figure 6. Deming's chain reaction (Adapted from Carrión-García & Grisales 2015)

The Plan-Do-Check-Act (PDCA) cycle (Deming 1986) provides a high-level framework for effective quality improvement process (Nanda 2005). The PDCA feedback loop steps and activities according to Juran (1998) are:

- **Plan** – choosing control subjects, setting goals
- **Do** – running the process
- **Check** – sensing and umpiring
- **Act** – stimulating the actuator for corrective action

Continuous improvement

Continuous improvement (CI) is a philosophy that can be defined generally as a culture of sustained improvement that targets elimination of waste in all systems and processes of an organization, by promoting co-operation of everyone to make improvements without requiring huge capital investments. CI can occur as evolutionary improvement (incremental improvements) or as radical changes originating from innovative ideas or new technologies. (Bhuiyan & Baghel 2005) Other definitions of CI in literature are presented as:

- *"a company-wide process of focused and continuous incremental innovation"* (Bessant et al. 1994)
- *"improvement initiatives that increase successes and reduce failures"* (Juergensen 2000)

The history of CI has been apparent since 1800s, where management promoted employee-driven improvements and incentive programs were established to reward employees that bring up positive changes in the organization (Schroeder & Robinson 1991). The focus of CI has been then changing from principles related to work improvement in the past, to modern day CI that focuses on organized and comprehensive methodologies involving the whole organization, or a large part of it, in change. During the last decades, the need to continuously improve the organization on a larger scale has become a necessity. Therefore, several CI methodologies have been developed on the concepts of quality or process improvement to reduce waste, simplify production, and improve quality. (Bhuiyan & Baghel 2005) According to Bhuyian & Baghel (2005), the best-known CI methodologies are lean manufacturing, six sigma, balanced scorecard and lean six sigma, which are characterized next:

Lean manufacturing was systematized by Henry Ford when establishing the concept of mass production in his factories and then adopted and improved by the Japanese. Lean manufacturing aims to systematically identify and eliminate waste through CI by monitoring the product at the pull of the customer. The lean manufacturing methodology includes eliminating waste in every area of production, including customer relations, product design, supplier networks and factory management. (Bhyian & Baghel 2005) The goal of lean manufacturing is to become highly responsive to customer demand and produce high quality products in the most efficient and economical manner possible. This can be achieved by removing the waste in firm's operation, involving less human effort, less inventory, less time to develop products and less space required. Lean methodology also promotes learning within the organization, as mistakes are considered as waste and therefore are not generally repeated. (Robinson 1990)

Six sigma is defined as "an organized and systematic method for strategic process improvement and new product and service development that relies on statistical methods and the scientific method to make dramatic reductions in the customer defined defect rates" (Linderman et al. 2003). The philosophy of this methodology is about minimizing defects to the level of accepting close to zero, focusing on variation reduction in all organizational processes. The DMAIC model was developed to achieve

this goal, including quality measurement that are applicable throughout the organization. DMAIC stands for: define opportunities, measure performance, analyse opportunities, improve performance, and control performance. The six sigma method has been successfully established in several top organizations (Motorola, GE, ABB, Honeywell) and is considered a mission-critical best practice even among SMEs. (Bhyian & Baghel 2005)

The balanced scorecard (BSC) is a method developed in 1990 by Robert Kaplan and David Norton, translating organization's objectives into measures, goals, and initiatives in four different perspectives. These four aspects are defined as financial, customer, internal business process and learning and growth. The BSC is used to translate the mission and vision of the organization into a wide set of objectives and performance measures that can be monitored and evaluated and to discover whether management is achieving desired results. The BSC allows feedback loops for all business processes, which are a necessity to achieve improvement. The method considers feedback from process outputs as well as business strategy outputs. The emphasis is placed on processes that need to be executed successfully for the success of an organization's strategy. (Bhyian & Baghel 2005) According to Niven (2002), the balanced scorecard consists of a measurement system, a strategic management system and a communication tool, which are described in table 1.

Table 1. The components of a balanced scorecard system (adapted from Bhyian & Baghel 2005).

Measurement system	The company's vision and strategy are translated into objectives and measures, instead of just focusing on financial measures (Bhyian & Baghel 2005). Measurable goals and objectives are considered as one of the most important aspects of a successful strategy (Gaplin 1997).
Strategic management system	The balanced scorecard helps aligning short-term actions with strategy, thus removing barriers towards long-term strategic implementation in the organization (Bhyian & Baghel 2005).
Communication tool	With the use of a balanced scorecard, the organizations strategy is clarified and brought to the average employee, thus allowing their contribution towards the overall goal of the organization (Niven 2002).

Lean six sigma is a hybrid methodology that has been developed after the apparent benefits of lean and six sigma. A combined CI program is considered more far reaching

than any one program individually and has been used to overcome the weaknesses of one program and to help the organization to get a bigger share of the market. With lean six sigma the required improvements can be achieved at greater rate than just using lean manufacturing or six sigma methodologies. (Bhyian & Baghel 2005) With lean six sigma, shareholders value is maximized by achieving the fastest rate of improvement in customer satisfaction, quality, cost, invested capital and process speed (George 2002). The model provides greater value to the customer. Lean focuses on elimination of waste, while six sigma focuses to reduce variation. Thus, waste is first removed, that allows for easier spotting of variations. With the fusion of the methodologies, the organization can maximize its potential for improvement. (Bhyian & Baghel 2005)

Nanda (2005) describes a continuous improvement model for project development projects, based on the PDCA cycle. The model is illustrated in figure 7. The model provides understanding on incremental improvements to organization's processes, use of tailored processes and identification of future process changes based on the process experience. (Nanda 2005)

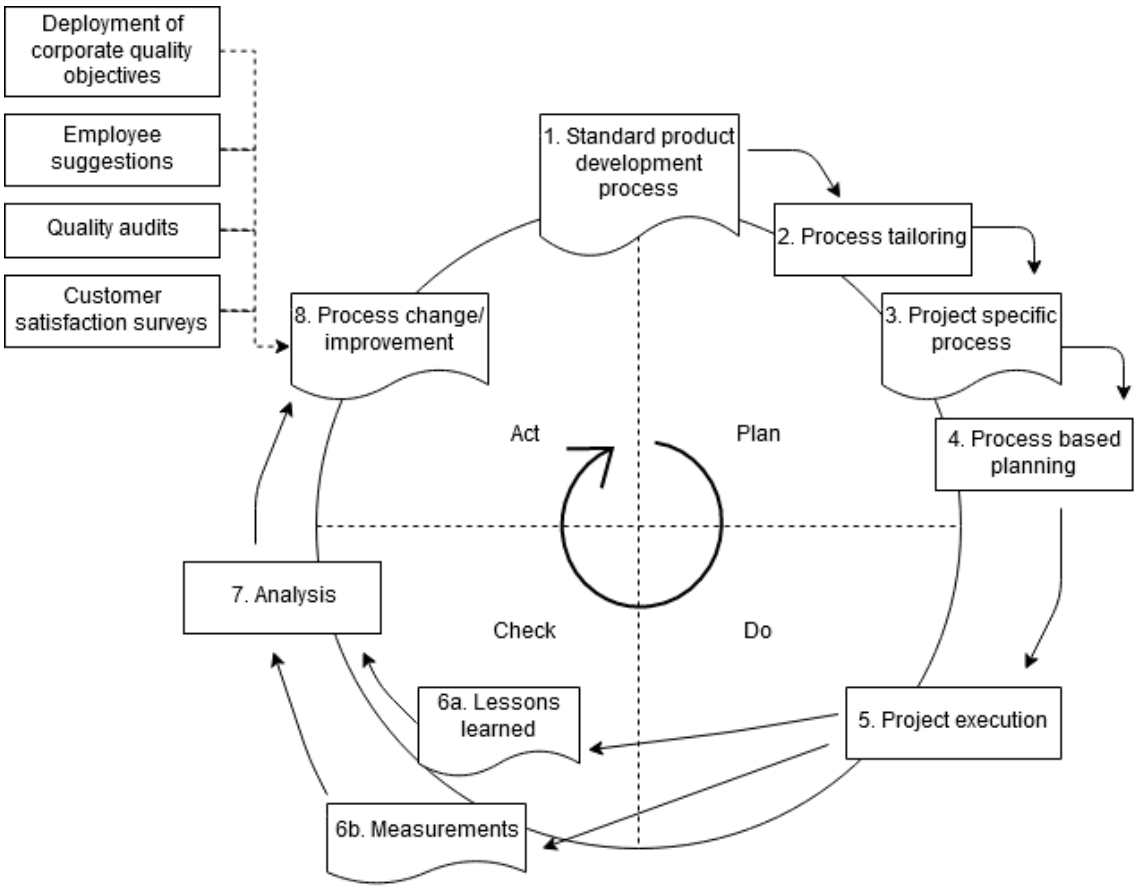

Figure 7. The CI cycle for PD process improvement. (modified from Nanda 2005)

- The improvement cycle begins with quality planning, where the standard product development (PD) project is tailored according to identified deviations from the process, supporting rationale and risk mitigation. The outcome of the process-tailoring activity is a list of planned process deviations, which are used to define the project-specific process. The defined process is then used as a basis for executing project planning activities in a process-based planning way. (Nanda 2005)

- Once the project plans for project-specific process are complete, the project is executed. After product development and validation activities, the product is released to the customers and the project formally concludes. The project conclusion is followed by a project post-mortem review to identify lessons learned, execute corrective and preventive actions and analyse project performance. The deficiencies discovered in the post-mortem review and in the analysis of measurement data are used to change processes as needed. The need for process change may also arise from quality audits, employee suggestions, customer satisfaction surveys or improvement actions for deployed quality objectives. (Nanda 2005)

- The defined process changes are then evaluated to make decisions to pilot or deploy the changes in the next project. Once the decision to deploy the changes in the process is made, relevant QMS documentation is updated to formalize the change. The updated PD processes and QMS documentation are then used as the basis for the next project, repeating the cycle. (Nanda 2005)

2.1.3 Total quality management

As organization develops its quality management methods to cover all parts of the organization, including customers and suppliers and their involvement in key business processes, the organization is on its way to implement total quality management (TQM) (Dale et al. 2009). TQM is a broad management approach that deals with processes and attitudes. In TQM approach, quality is placed as the primary objective for the

organization, opposing traditional management goals of maximising production and controlling costs (Pardeep 2013). TQM requires application of quality management procedures on every level and branch of operations, promoting its integration into business practices and having a balance between managerial, technical and people issues. Total quality management is an approach to quality, covering the whole organization and involving every person in continuous improvement (Dale et al. 2009). TQM can be also be used as a multidimensional approach to measure organizational performance, equally considering both financial and non-financial measures (Sila 2007).

Implementing TQM also requires improvements in personnel working on quality assurance level, in the form of expanding outlook and skills and increasing their creative functions. By implementing total quality management philosophy, several improvements are to be expected, such as more evolved tools and techniques, more emphasis on people, established process management, better training and personal advancement and more focus on eliminating waste and non-value-adding activities. Organization's activities will be more customer oriented and focusing on delighting them instead of just satisfying. (Dale et al. 2009)

Building blocks of TQM organization

While several different views on the composition of TQM exist, there are established key elements that compiles TQM, according to Dale et al. (2009). The key elements are presented in table 2.

Table 2. The key elements of TQM (modified from Dale et al. 2009)

Commitment and leadership	Without the commitment of executives/senior managers, not much happens and it won't be permanent. The role of executives is to take personal charge of improvement, control the process, show direction, and have a strong grip on leadership, i.e. by controlling personnel that hinder the improvement process.
Planning and organization	Planning is required to form a long-term strategy for TQM, that is integrated with other organizational strategies (IT, operations, business plans). It helps to develop quality straight into designs and processes, adds prevention-based activities, corrects quality assurance procedures to ensure correct operation of closed-loop corrective actions, lines quality systems and related procedures with overall strategy, develops the improvement supporting organization and infrastructure and pursues towards standardization of systems, procedures and work

	guides.
Tools and techniques	By using quality tools and techniques in a problem-solving sense, the process of improvement can be started, employees using them will feel involved in the improvement, quality awareness is improved, and attitudes change towards favouring improvement.
Education and training	Education and training should be provided, to ensure that employees on every level of the organization have general awareness and understanding regarding quality management related skills, competencies and concepts to suit continuous improvement philosophy and to have a common language when addressing quality management related topics throughout the business. If training is lacking or completely missing, a change in behaviour and attitudes won't happen.
Involvement	To make every employee in the organization genuinely involved in the continuous improvement process, all types of means to achieve employee interest must be taken into consideration, i.e. in the form of teamwork activities. Through involvement personnel will get better understanding about their role and how their tasks relate to the whole business picture. They also gain knowledge of how their relations and dependencies are between them and their internal customers.
Teamwork	Teamwork is important part of involvement and provides means in gaining commitment and participation throughout the organization, while also maximizing the value and output of individuals.
Measurement and feedback	Internal and external indicators provide encouragement that things are improving with measurable facts. Measurements allow an action plan to be developed to meet the set targets and bridge gaps.
Ensuring that the culture is conductive to continuous improvement activity	Organizational culture that is conductive to continuous improvement and in which everyone can participate requires changing people's behaviour, attitudes and working practices and also integrating quality assurance into all organization's processes and functions. Change management is seen as one of the greatest challenges facing a company that implements or improves their QM procedures to achieve TQM in the organization.

2.1.4 Software quality management

Quality is considered an important requirement of software products, a competitive necessity, and a business essential. Strong quality focus is given to all phases of the software development lifecycle, and emphasis is increasing on product quality, process maturity and continual process improvement. (Murugesan 1994) Software applications are nowadays "systems of systems", consisting of hardware, networks, software services and users. Systems themselves have become software-intensive, heterogenous and dynamic. Thus, a lack of software quality is seen problematic from several aspects.

To achieve these demanding levels of quality, a software quality process is essential for an organization. A software quality process is the result from defining the software quality attributes, that allow the organization to define quality and required quality levels. The defined attributes allow the definition of quality requirements for the target system. A proactive way of quality assessment is required to determine when system attributes may fail to meet the set requirements. (Mistrík et al. 2016)

A challenge with new development methods such as agile method is testing of the software. Software testing can be viewed as the cornerstone of software quality management practices. (Mistrík et al. 2016) Shortcoming in software testing leave a greater number of errors undetected and uncorrected, and therefore affecting the error rate. Shortcomings may originate from causes such as: incomplete test plans, failures to document and report errors and faults, failure to correct detected software faults as a result of insufficient indications of the reasons for the fault, or negligence or time pressures that lead to incomplete correction of the error. (Galin 2004)

Software quality management (SQM) includes processes that ensure that software products, services and life-cycle process implementations meet the quality objectives of an organization and achieve stakeholder satisfaction (Galin 2004; Schulmeyer 2007; Tian 2005). SQM consists of three basic subcategories: software quality planning (SQP), software quality assurance (SQA) and software quality control (SQC). Also, software process improvement (SPI) is often considered a sub-category of SQM process. The SQM elements are presented in figure 8. (Mistrík et al. 2016)

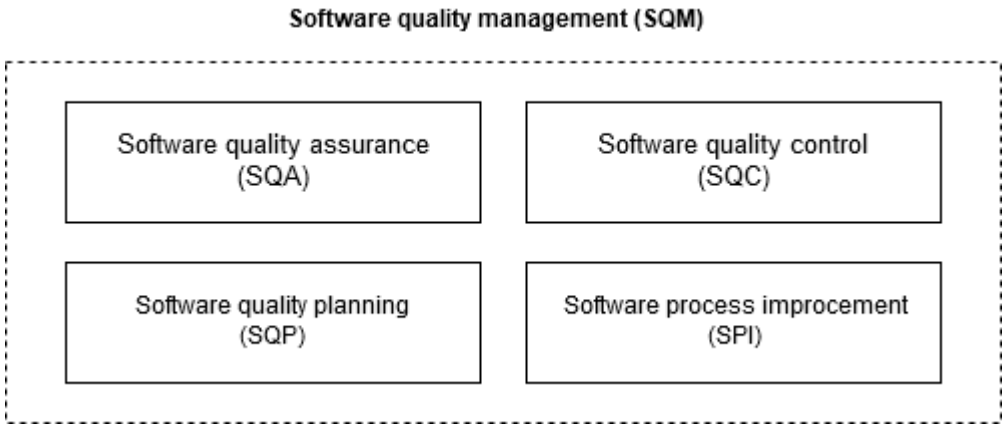

Figure 8. Main elements of SQM (adapted from Mistrík et al. 2016)

SQC activities focus on examining product artefacts' (such as code, design, documentation) compliance to established project standards (functional and non-functional requirements and constraints) and ensures that these artefacts are checked for quality before their delivery. Typical SQC activities include code inspection, technical reviews, and testing. (Mistrík et al. 2016)

SQA plays a critical role in software development lifecycle (SDLC) and can affect project's overall success. It is defined as a repeatable process that is integrated with project management and software development lifecycles. Objective of the SQA process is to assure conformance to requirements, reduce risk, assess internal controls, improve quality and to conform to stated schedule and budget of the project. (Owens & Khazanchi 2009) Gill (2005) views SQA as an umbrella activity applied to each step of a software process, involving mapping of managerial precepts and design disciplines of quality assurance onto the space of software engineering. If attention is not paid to SQA activities, the consequence may be in the form of budget overruns, schedule delays, failure to meet project objectives or poor customer satisfaction (Chow 1985). Quality assurance practices can reduce project failures with checks throughout the SW project process (Owens & Khazanchi 2009). Feldman (2005) states that SQA provides assurance and credibility that the project works correctly. The IEEE standard (IEEE Std 610.12-1990, 1991) defines SQA in following ways:

- "a planned and systematic pattern of all actions necessary to provide adequate confidence that an item or product conforms to established technical requirements"
- "a set of activities designed to evaluate the process by which products are developed or manufactured"
- "the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality"

- "part of quality management focused on providing confidence that quality requirements will be fulfilled." (IEEE Std 610.12-1990, 1991)

SQP is defined at the project level in alignment with the SQA. The planning specifies the project commitment to follow standards, regulations, procedures, and tools during the software development lifecycle. SQP also defines quality goals, expected risks and risk management, along with estimated effort and schedule of software quality activities. An SQP may include SQA components, or it may be customized based on the project's needs. (Mistrík et al. 2016)

Several software quality factor models have been suggested over the years. McCall's factor model, consisting of 11 software quality factors that are grouped into three categories (McCall et al. 1977), is considered as the classic factor model (Galin 2004) and continues to provide a practical and up-to-date method for software requirement classification (Pressman 2000). The McCall's factor model categories include product operation, product revision and product transition. The three categories and included factors are presented in figure 9.

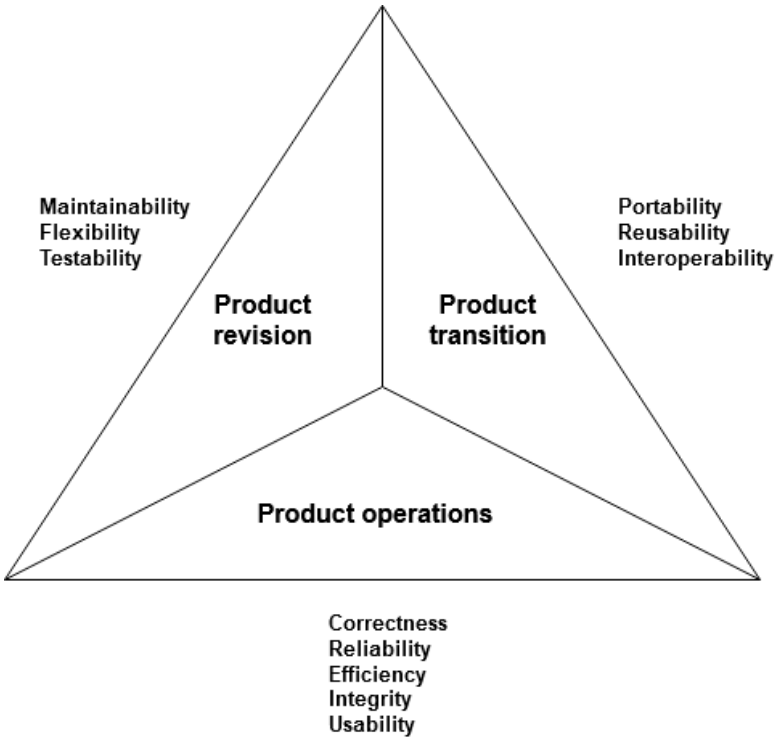

Figure 9. McCall's software quality factors (adapted from Venters et al. 2014).

2.1.5 Benefits of quality management

One of QM's main strengths is in the consideration of the socio-technical system of an organization (Manz & Stewart 1997). Internally, QM promotes social aspects in an organization, such as teamwork and autonomy, by increasing self-regulatory capability of groups and individuals (Molina et al. 2007). Externally QM enhances cooperation with customers and suppliers in a non-competitive manner, to build and maintain an open relation with them (Flynn et al. 1994).

Quality management practices are also found to have a positive impact on organizational performance (Lakhal et al. 2006; Jaafreh 2013). A significant relationship between QM dimensions (leadership, strategic planning, customer focus and employee relation) and organizational performance is shown in a study carried out by Jaafreh (2013). A positive relationship is found between TQM constructs and firms' inventory management performance, quality performance and financial and market performance (Kaynak 2003). Beckford (2002) divides the motivation for QM into three arguments:

- **The economic argument** – quality improvement increases revenues and decrease costs.
- **The social argument** – the production of non-quality goods is a waste of human resources and talent. Non-quality environment is demoralizing for its' employees.
- **The ethical argument** – world has limited resources; therefore, they should not be wasted for non-quality goods. (Beckford 2002)

2.1.6 QM adoption in SMEs

Small and medium-sized enterprises (SMEs) often end up working with QM when large companies, whose suppliers the SMEs are, demand so. However, as Ghobadian and Gallear (1997) state, QM in SMEs is not restricted to their relationship with larger companies, but the adoption of QM can effectively help the firm's transition from the incubation stage to the maturity stage. Ghobadian and Gallear (1996) state that the basic concepts of QM are equally applicable to SMEs and larger companies, but the detail and

method of implementation differ. Kumar and Anthony (2008) state that QM initiatives can be adopted in both small and large companies. However, QM has not been adopted in smaller companies to any greater degree (Achanga et al. 2006). Common characteristics for SMEs, that have effect on quality management context are presented in table 3.

Table 3. Common characteristics of SMEs (modified from Assarlind & Gremyr 2014)

Structure	• Flat structure with few layers of management • Large degree of influence exercised by individual managers • Informal strategies • Single sited • Potential for quick responses to external charges • Low degree of specialisation • Unified culture • Limited financial resources
Contacts	• Operating in limited markets with a small customer base • Limited external contacts
Processes	• Flexible processes • Low degree of standardisation • Reactive and firefighting mentality • Result-oriented
People	• Modest human capital and know-how • Very few internal change catalysts • Individuals can see the results of their efforts • Low incidence on unionisation

Price and Chen (1993) list five challenges facing QM implementation in SMEs:

1) Senior managers are used to micro-manage all aspects of a small firm.
2) Every team in the organization must be empowered equally
3) Lack of resources leads to slower solving of quality issues, which then leads to frustration and scepticism among the employees
4) Motivating employees during the early activities might be difficult, as the results cannot be shown quantitatively
5) Training works best when there is a class size of 10 or more. For small firms it might not be possible to continue daily operations if a sizable portion of employees are attending class.

Assarlind (2014) summarizes six critical factors for QM initiatives in SMEs from literature:

1. Contextualization - Building the QM on the company's current strengths.
2. Gradual implementation using realistic goals - A stepwise method of implementing QM with continuous monitoring to show the achieved benefits and early profits.
3. Involvement and training of employees - Involvement is reinforced by sharing information, communicating, training, recognition and rewarding of accomplished QM work.
4. Involvement of external support - it might be required to educate or employ a person with QM skills, to support the implementation
5. Management involvement - Management's role is to spread an awareness and understanding of QM, to support the implementation
6. Fact-based follow-up - Measuring the effectiveness of QM, to ensure that improvements are made and that they align with the set goals

2.2 Process management

Establishing and improving a process management infrastructure is widely accepted view in improving the quality of products and services of an organization (Nanda 2005). A simple way to define a process is transformation of a set of inputs into outputs. The outputs satisfy internal and external customer needs and expectations and can be in the form of products, information, or services. In an organization, every department includes processes that can be analysed through their inputs and outputs. Cross-functional processes can be evaluated in the same manner of looking into their inputs and outputs. (Oakland 2014)

Business process mindset provides analytic view on processes and breaks the mould of only focusing on processes of separate functional units (Hammer 1996). The focus of managing business processes is to improve processes and thus ensure that critical activities that affect customer satisfaction are optimized in efficiency and effectiveness. Successful implementation of business process management is tied to two key concepts:

process alignment and people involvement. (Hung 2006) Effective process management requires consideration of voice of the customer and voice of process, which are used to form the process equation: right suppliers + correct inputs = correct outputs + satisfied customers. This process is also known as the SIPOC process, presented in figure 10. (Oakland 2014) SIPOC stands for suppliers, inputs, process, outputs, and customers (Rasmusson 2006).

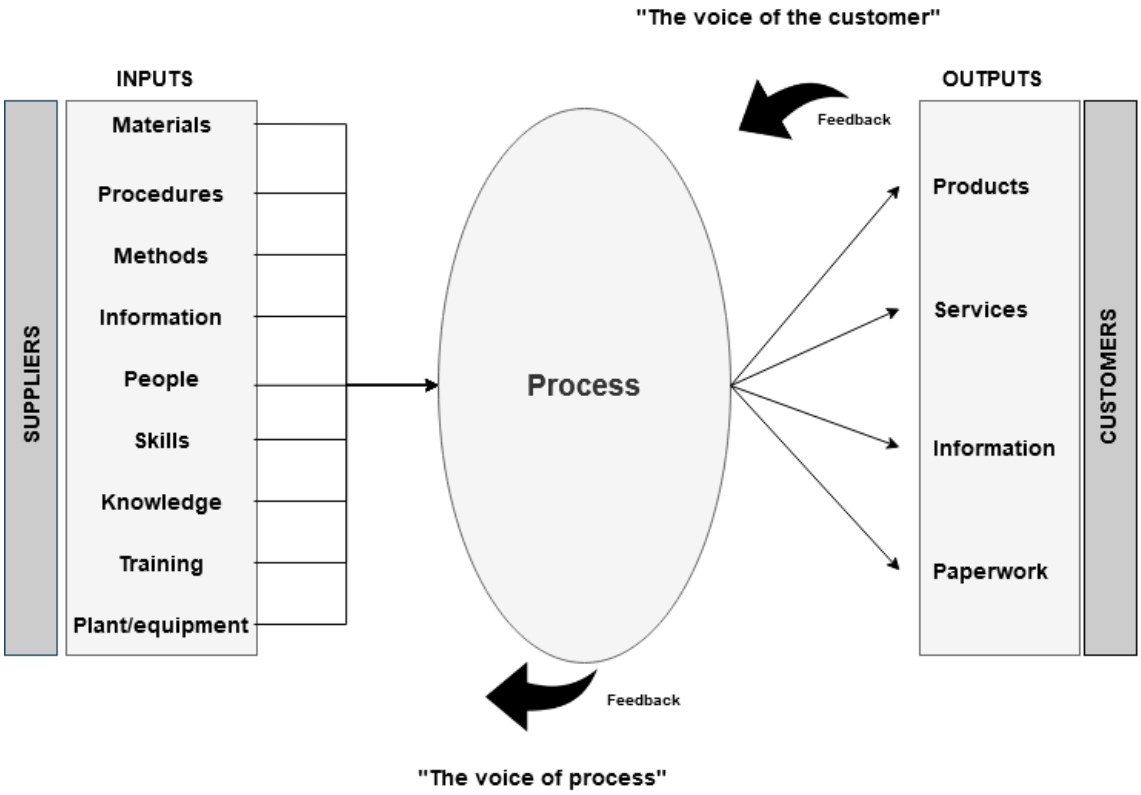

Figure 10. The SIPOC process (adapted from Oakland 2014)

Oakland (2014) describes the best process management practices as following:

- Identification of key business processes
- Systematic process management
- Reviewing processes and setting improvement targets
- Innovation and creativity-based process improvement
- Adjusting processes and evaluating the benefits

Juran (1998) describes three methods for selecting key processes of an organization, that process management should prioritize. The key processes can be selected with the critical success factor (CSF) method, the balanced scorecard method or by evaluating processes through identified organization-specific critical selection criteria. The resulting key processes are displayed graphically with process maps. (Juran 1998) Mapping business processes is an important factor in understanding flow of information and resources within the internal value chain. It also helps understanding relationships between different processes and dimensions. Process mapping also benefits performance assessment in operational and support processes. (Carpinetti et al. 2003)

2.3 Performance measurement

Performance measurement is important to achieve sustainable improvement within an organization (Lee & Ahn 2008). Measurements play a key role in quality planning and improvement by tracking progress against goals, identifying opportunities for improvement, and comparing performance against internal and external standards. Measurement, together with analysis and improvement processes demonstrate that products, services and processes meet the required specifications. (Oakland 2014). Tracking key processes in the critical process steps with in-process and result measures helps to meet customer requirements, prevent errors, improve cycle time, increase productivity and reduce variability (Lee & Dale 1998).

Key performance indicators (KPIs) are top-level business indicators that are used to drive the business at top level. Performance metrics on the other hand, support the KPIs and drive the lower level progress of business, departments, and projects. The concepts of KPIs and performance metrics should not be mixed, but their direct link to each other is crucial. (Boltic et al. 2010)

Oakland (2014) presents a systematic model for a performance measurement framework (PMF), that is based on strategic planning and process management. The framework consists of four elements: strategy development and goal deployment (level 1), process management (level 2), individual performance management (level 3) and performance review (level 4). These four levels are described more closely:

- The first level of PMF, strategy development and goal deployment, begins at identifying critical success factors (CFSs) based on mission statement. The CFSs should cover stakeholder groups, customers, employees, shareholders, and society. Performance measures for set CFSs are developed as key performance outcomes (KPOs) and targets for each CFS.
- On the process management and measurement level, processes are identified and mapped and organizational goals, action plans and customer requirements are translated into process performance measurements, known as key performance indicators (KPIs).
- The third level, individual performance and appraisal management, focuses on controlling individual performance. Direct managers have the responsibility of performance appraisal of individuals. Important steps on this level is identifying and documenting job descriptions, developing personal performance measures, define targets for performance targets, manage performance by planning tasks and managing their performance and identify areas of improvement.
- Performance review level includes identifying needs for performing a review, determining review methods, executing the reviews, and using the results in organizational or process planning level. (Oakland 2014)

2.4 Costs of Quality

Quality costs do not have a single clear generally agreed, precise, definition. Years ago, cost of quality was perceived as the cost of running the quality assurance department and laboratory along with scrap and warranty costs. Nowadays, the definition has evolved, and costs of quality are the costs from setting up and operating a quality management system, costs from continuous improvement process and failures of processes, products and services. Quality costs are considered cross-organizational, as they can arise from a range of organizational activities, such as from sales and marketing, design, storage, production planning, operations, or installation procedures, to name a few. The costs can also originate from outside of the organization, such as from suppliers, distributors, or customers. Typically, quality-related costs range from 5

to 25 % of a company's annual sales turnover, depending on the industry and the company's way to manage quality and the improvement process. (Dale et al. 2009)

The objective of a cost of quality (CoQ) system is to find the quality level which minimizes the total cost of quality. (Shiffauerova & Thomson 2006) A company can also identify places to optimize costs by analysing quality costs (Janis 2012). Costs associated with poor quality is measured for three reasons: to quantify the size of quality problem to justify improvement efforts, guide the development on that effort and to track progress of improvement activities. Cost of poor-quality components are presented in figure 11 (Juran 1998).

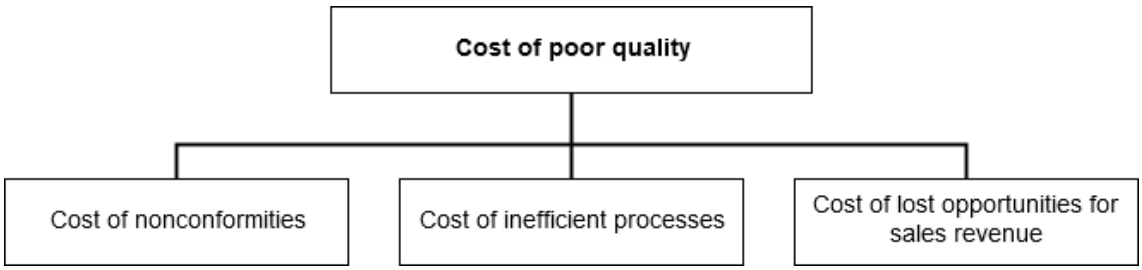

Figure 11. The cost of poor-quality components (modified from Juran 1998)

Measuring and reporting the cost of quality should be considered an important issue in the company. Cost of quality approach is evidently effective in reducing company's quality costs and improving quality for their customers. Still, it is not utilized in most quality management programs. A survey by Schiffauerova & Thomson (2006) compares different models for CoQ presented in the literature, including the most implemented classical prevention-appraisal-failure (P-A-F) model. To make the CoQ model a successful systematic tool in company's quality management program, the selected model must suit the situation, environment, purpose, and the needs of the company. The objective of continuous improvement programs is to meet customer requirements and to do it with the lowest cost. The reduction of the costs needed to achieve quality is only possible if they are first identified and measured. Generic CoQ models and their corresponding cost and activity categories are presented in table 3. (Shiffauerova & Thomson 2006)

Table 3. Generic CoQ models and cost categories (modified from Shiffauerova & Thomson 2006)

Generic model	**Cost/activity categories**
P-A-F models	prevention appraisal failure
Crosby's model	conformance non-conformance
Opportunity or intangible cost models	prevention appraisal failure opportunity --- conformance non-conformance opportunity --- tangibles intangibles --- P-A-F (failure cost includes opportunity cost)
Process cost models	conformance non-conformance

Juran (1998) defines the common quality cost categories as:

- **Internal failure costs** – costs of deficiencies (fail to meet explicit requirements or implicit needs of external or internal customers) discovered before delivery, avoidable process losses and inefficiencies. These costs would disappear with zero deficiencies.

- **External failure costs** – costs associated with faulty products that have reached the customer, lost opportunities for sales revenue. These costs would also disappear with zero deficiencies.
- **Appraisal costs** – costs that arise from determining the product's degree of conformance to set quality requirements, such as incoming inspection and product quality audits.
- **Prevention costs** – costs caused by keeping the failure and appraisal costs to a minimum, such as quality planning and process planning activities. (Juran 1998)

The P-A-F model is the most employed in the companies that use quality costing. The basic understanding of the model is that investment in prevention and appraisal activities will lead to reduced failure costs and further investment in prevention activities will reduce appraisal costs (Porter & Rayner 1992). Crosby's model's cost categories share similarities with P-A-F scheme. The cost of quality in Crosby's model consists of the sum of price of conformance and price of non-conformance. Conformance costs include making certain that things are done right the first time, including actual prevention and appraisal costs. Price of non-conformance includes money that is wasted when the work fails to meet the customer requirements, calculated by determining the cost of corrective actions, reworking or scrapping, corresponding to actual failure costs. (Shiffauerova & Thomson 2006) Many times the P-A-F model and Crosby's model are used in companies in the same way, and the only difference is the terminology related to these CoQ models. (Goulden & Rawlins 1995) Both models have been successfully implemented in several companies and industries. (Shiffauerova & Thomson 2006)

Opportunity and intangible costs have gained importance recently. Intangible costs can be only estimated, such as lost profits from lost customers and reduction in revenue caused by non-conformance. (Shiffauerova & Thomson 2006) According to Sandoval-Chavez and Beruvides (1998), opportunity costs can be divided into three components: installed capacity underutilization, inadequate material handling and poor service delivery. These losses are added into traditional P-A-F quality expenses, so that total CoQ is expressed as revenue lost and profit not earned. Modaress and Ansari (1987) also promote expanding the P-A-F model with extra dimensions of cost of inefficient

resource utilization and quality design cost. Carr (1992) divides the quality costs into three categories: the cost of conformance, the cost of non-conformance and the cost of lost opportunity. Opportunity and intangible costs have been implemented in CoQ improvement programs with positive results. The company Xerox was the first company to implement opportunity cost to determine CoQ, which resulted in an 83 % reduction in CoQ as well as improved customer satisfaction (Shiffauerova & Thomson 2006).

The process cost model focuses on process rather than products or services (Marsh 1989), collecting and analysing quality costs for both direct and indirect functions (Goulden & Rawlins 1995). Process cost consists of the total cost of conformance and non-conformance for a specific process. The cost of conformance presents the cost of producing products or services first time meeting the requirements of the specific process, and non-conformance is the failure cost caused by process not meeting the required standard. Process costs allow to determine if more failure prevention activities are needed in the process or if excessive conformance costs show the need for a process redesign. The process cost model is applicable within total quality management as it promotes the importance of process cost measurement and ownership and provides a more integrated approach to quality compared to the P-A-F model. (Porter & Rayner 1992) Process modelling is strongly related to the model. Crossfield and Dale (1990) promote a method to map the quality assurance procedures, information flows and quality-related responsibilities. Other methods exist as well, such as hybrid model representing the main processes using flowcharts (Goulden & Rawlins 1995).

An activity-based quality costing (ABC) model is developed by Cooper and Kaplan (Cooper 1988; Cooper & Kaplan 1988) to help allocating overheads to CoQ elements and tracing quality costs to their sources (Tsai 1998). It is not considered an actual CoQ model, but an alternative approach that helps to manage quality costs more effectively by identifying, quantifying and allocating quality costs among products. In the ABC model, resource costs are traced to their respective activities and the cost of these activities to cost objects, thus achieving accurate costs for different cost objects. The long-term goal of an ABC system is to remove non-value-added activities and to continuously improve processes, activities and quality, so that no defects are produced (Shiffauerova & Thomson 2006).

CoQ parameters and metrics

Generally, CoQ measurement system should include good feedback metrics and a mixture of global and detailed metrics. The metrics are the elements of CoQ and how their performance is measured. For example, the measurement system can include the cost of defects per 100 pieces produced, the time between service calls, the number of complaints received or the cost of assets and materials as detailed metrics. For global metrics, literature suggests the following metrics presented in table 4. The most frequently mentioned metric is return on quality (RoQ), which is used as a basis for accepting quality improvement projects in companies and it is also used as a tool to compare the suggested quality improvement projects (Shiffauerova & Thomson 2006). RoQ have been also modified to fit in the software environment with three new quality metrics: return on software quality, cost of software quality and software quality probability index (Slaughter et al. 1998).

Table 4. Global metrics for CoQ system (modified from Shiffauerova & Thomson 2006)

Metric
RoQ = $\frac{increase\ in\ profit}{cost\ of\ quality\ improvement\ program}$
Quality rate = $\frac{input - -quality\ defects + startup\ defects + rework)}{input}$
Process quality = $\frac{available\ time - -ework\ time}{available\ time}$
First time quality = (% product with no rework)

2.5 Quality management systems

ISO 9000:2015 defines quality management system (QMS) as “part of a management system with regard to quality” (ISO 2015). A QMS works as an established framework of reference points, ensuring that every time a process is performed, the same information, methods, skills, and controls are used and applied. As a result, the system helps to define requirements, communicate policies and procedures, monitor work

performance, and improve teamwork. (Dale et al. 2009) A QMS should cover all processes in the organization, aiming to accomplish the objectives of the quality policy. This is done by controlling human, administrative, and technical factors that influence quality. A good QMS ensures that both customer's requirements and organization's requirements and met and objective evidence is collected. (Oakland 2014) The primary motivation for implementing a QMS is either management need (e.g. to improve productivity or product quality) or customer demand. Sometimes competitive pressure drives the QMS implementation in an organization. (Nanda 2005)

Documentation of the QMS is crucial to quality assurance and takes several forms. All aspects of an organization's operation should be described in the QMS, along with relevant activities. A QMS is a management practice that covers organization, responsibilities, procedures, and processes. (Dale et al. 2009) A QMS is a permanent part of an organization, including a structure, a defined scope, responsibilities, content related to processes and supporting QMS documentation and resources to accomplish quality planning, QC, QA, and continuous quality improvement. A QMS must be improved continuously to maximize its efficiency and effect on an organization. (Nanda 2005) Dale et al. (2009) present a QMS documentation structure that consists of four levels, which are presented in table 5.

Table 5. The QMS documentation levels (adapted from Dale et al. 2009)

Level 1.	A company quality manual. Provides a compact statement of the quality policy and quality objectives (Dale et al. 2009) ISO 9000:2015 defines quality manual as "specification for the quality management system of an organization" (ISO 2015).
Level 2.	A procedures manual. The manual gives structure to the QMS, describes how the system functions, allocates responsibilities for each department/unit and states the practices to be followed in the organization.
Level 3.	Work instructions, specifications, methods of performance and detailed work methods together form the third level of documents.
Level 4.	All other reference documents, such as forms, standards, drawings etc. (Dale et al. 2019)

2.5.1 ISO 9000 series QMS standards

The ISO 9000 standard series create a link between the quality of the management system to product and process quality, by focusing on customer satisfaction and continuous improvement (Oakland 2014). The ISO 9000 series of International

Standards were first published in 1987 to support the growing internationalization of business, to provide common QMS standards (Fonseca 2015) and to build confidence between manufacturers and suppliers in B2B transactions and in international trade (van der Wiele et al. 2004). The series of standards describe the specific minimum characteristics of quality systems that can be standardized, benefitting organizations and their suppliers by letting each other know that they meet certain requirements (Tummala & Tang 1996). ISO 9001 represents a management model that combines proven principles and concepts to develop the capability of an organization (Hoyle 2017).

ISO 9000 standards focus on the assurance of quality consistency rather than quality improvement on the products or services of an organization (Tsiotras & Gotzamani 1996). The standard series help organizations to ensure that they follow specific well-documented procedures in the making and delivering their products, guaranteeing that the products or services are in accordance with customer specifications (van der Wiele et al. 2004). The certification of ISO 9000 series only details the essential elements of a formal QA system, not the ways to apply them. Therefore, it is stated that the certification cannot be applied in the same way in every organization. (Tsiotras & Gotzamani 1996).

The ISO 9000 standard series promotes process approach when developing, implementing, and improving the QMS. The process approach in a QMS enables understanding and consistency in meeting requirements, consideration of added value in processes, achievement of effective process performance and process improvement based on data and information. A schematic representation of any process and its elements is presented in figure 12, with possible monitoring and measuring check points necessary for process control. (ISO 2015)

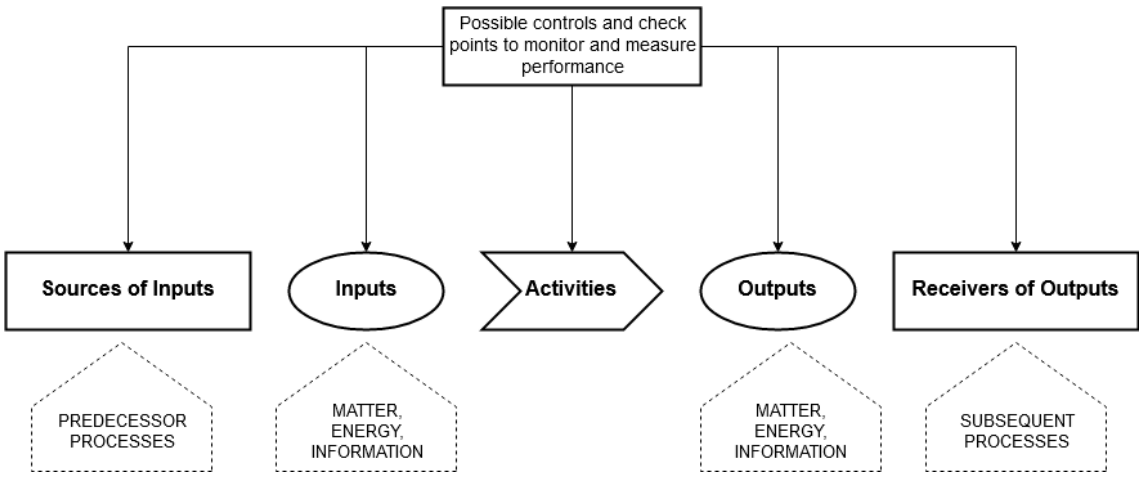

Figure 12. Elements of a single process (modified from ISO 2015)

The structure of ISO 9001:2015 follow the ISO Directives Annex SL, which is a general requirement for all management system standards (Anttila & Jussila 2017). The structure, chapters, and clauses of the ISO 9001:2015 according to ISO Directives Annex SL are listed in table 6.

Table 6. The ISO 9001:2015 standard structure (modified from ISO 2015)

1 - 3 General introductory clauses	**4 Context of the organization** 4.1 Understanding of the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.3 Determining the scope of the quality management system 4.4 Quality management system and its processes
5 Leadership 5.1 Leadership and commitment 5.2 Policy 5.3 Organizational roles, responsibilities and authorities	**6 Planning** 6.1 Actions to address risks and opportunities 6.2 Quality objectives and planning to achieve them
7 Support	**8 Operation**

7.1 Resources 7.2 Competence 7.3 Awareness 7.4 Communication 7.5 Documented information 7.5.1 General 7.5.2 Creating and updating 7.5.3 Control of documented information	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and development of products and services 8.4 Control of externally provided processes, products and services 8.5 Production and service provision 8.6 Release of products and services 8.7 Control of nonconforming outputs
9 Performance evaluation 9.1 Monitoring, measurement, analysis and evaluation 9.2 Internal audit 9.3 Management review	**10 Improvement** 10.1 General 10.2 Nonconformity and corrective action 10.2 Continual improvement

The Annex SL structure includes typical managerial entities that are found in any organization's business system. The structure is used e.g. in information security management, environmental management, and asset management system standards. The harmonized management system structure helps organizations to integrate several different managerial systems simultaneously. (Anttila & Jussila 2017)

The clauses 4 to 10 of the standard can be grouped in relation to the beforementioned PDCA cycle to improve processes and the QMS. The PDCA cycle and standard clause relation is presented in figure 13. Numbers in brackets show the corresponding clause in the standard.

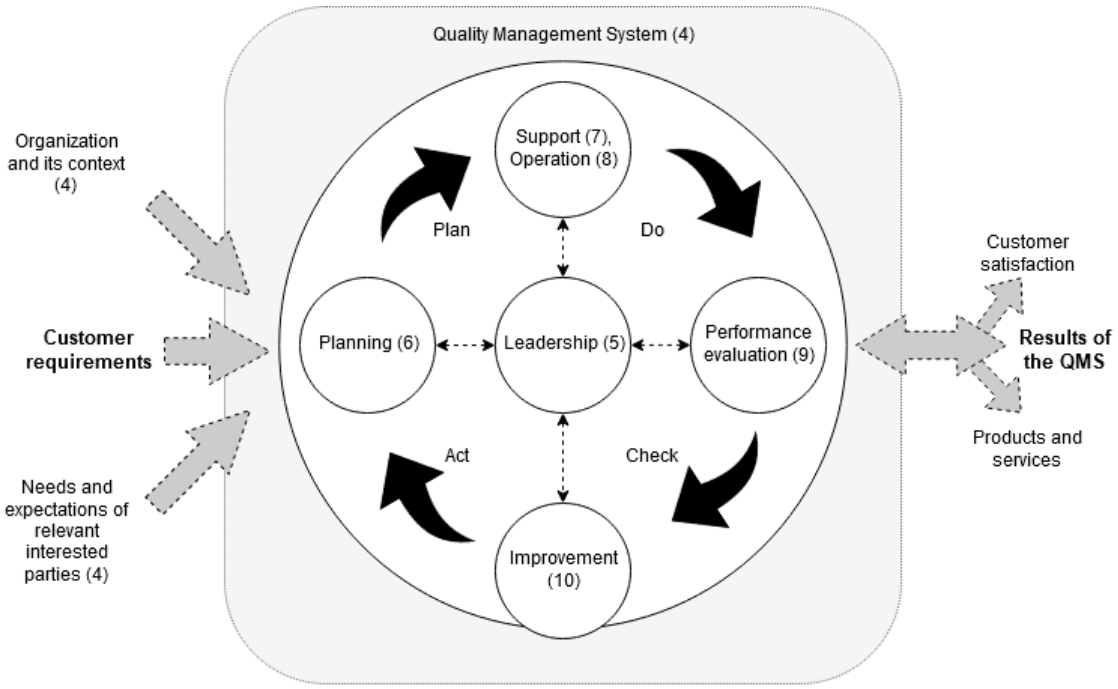

Figure 13. Structure of ISO standard in the PDCA cycle (modified from ISO 2015).

Priede (2012) summarizes the main reasons to implement an ISO 9001 based quality management system:

1. Consistency of output – well defined and documented processes and procedures are easily understandable for all employees and therefore contribute to the main idea of the standard, to do all things right at first time.
2. Information flow from processes to the top management – constant measurement of quality (to see if the processes running as defined and process mean deviation information).
3. Corrective actions are taken whenever defects occur – measurements give information about the defects, which the corrective actions are based on. Procedures, such as analysing causes and defining preventive actions support the process (tools such as Ishikawa diagram).
4. Decreased defect rates – the result from identifying and understanding problems and defining appropriate preventive actions.

5. Early spotting of defects, lower cost of defect correction – Well written procedures and the control over the whole process allow problem identification at a very early stage.
6. Documented procedures are easy to follow for new employees and assure that new employees will start to work effectively in a quick manner.
7. Retain or increase market share of the organization, increasing sales or revenues.
8. Lower production costs – through less nonconforming products and rework, lower rejection rates, streamlined processes and fewer mistakes.
9. Some markets require the standard or favour companies with ISO 9001 certification. (Priede 2012)

2.5.2 Self-assessment

Organizations that evaluate and take actions on improvements are found to advance and excel, compared to competitors. Self-assessment allows for explicit identification of organization's strengths and improvement areas and is therefore considered as a powerful organizational learning tool, directing the improvement process. (Lasrado 2018). An appropriate performance measurement system is essential for the organization to regularly check what activities are going according to plan, if there is a decline, determine development needs and to see what the gaps are between desired and actual results (Yang et al. 2001). Samuelsson and Nilsson (2002) divide self-assessment practices into two categories:

- Self-assessment related to the ISO standard, relating to QA self-assessment or audits, ensuring that required standards are met.
- The second type is based on an excellence model that originates from the TQM philosophy (Samuelsson and Nilsson 2002)

Organizations may use either a standardized quality model or an academic model as a reference for self-assessment of the organization (Lasrado 2018). Popular standardized and internationally recognized quality models include models such as the Malcom Balridge National Quality Award model (MBNQA) in the USA, the EFQM excellence model in Europe and the Deming Application Prize model in Japan. The models and guidelines for application help the management to define TQM for all types of

organizations. Usually the award models are usually not applied for the respective awards by organizations, but to simply use the criteria of the chosen model to examine and analyse the state of their improvement process and to guide how to achieve business excellence. (Dale et al. 2009) Next, the popular self-assessment models are described more closely.

The European (EFQM) model consists of customer satisfaction, people satisfaction and impact on society, and how they are achieved through leadership, strategy and management of people and resources. The model is divided into enablers, such as leadership, people, policy and strategy, and processes and resources. The enablers secure the "results", such as the improved satisfaction of people, customers and stakeholders, and improved business results. (Dale et al. 2009) The actual model criteria of the 2013 version of the model is presented in figure 14. EFQM Business Excellence Model is stated to bring relevant benefits to the organization, such as holistic and integrated approach, defined relationships between approaches and results and reinforced system dynamics (Dahlgaard-Park 2008). The model provides a framework for organizations to recognize their current maturity state in different scoring categories:

- <300 global scoring points – EFQM Committed to Excellence
- 300-500 global scoring points – EFQM Recognized for Excellence
- >500 global scoring points – EFQM Excellence Award, including three sub-levels, Excellence Award Finalist, Excellence Award Silver Prize and Excellence Award Gold Prize. (Fonseca 2015)

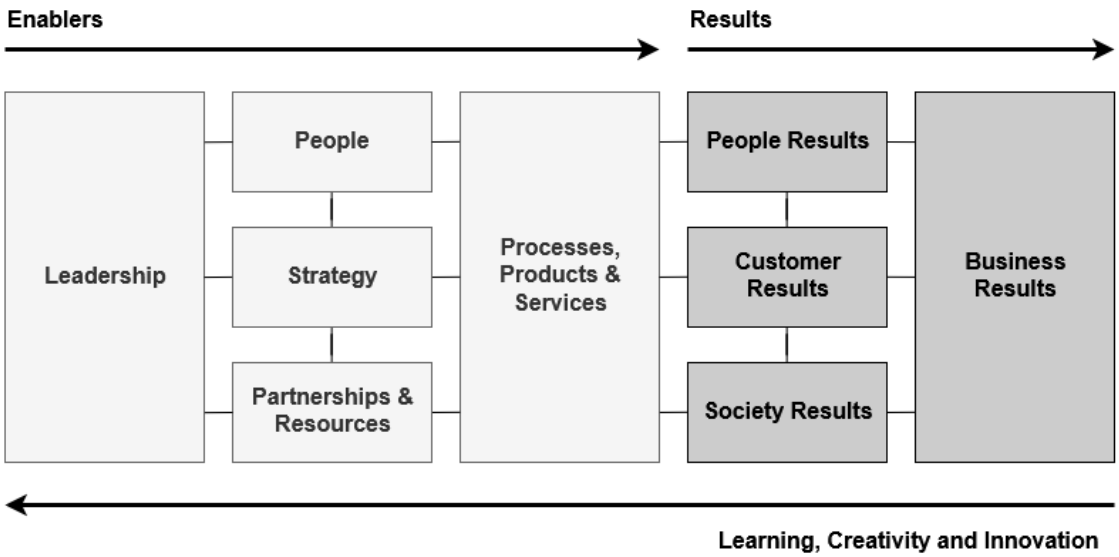

Figure 14. The EFQM 2013 Business Excellence Model (modified from EFQM 2012)

The MBNQA is a comprehensive framework used as a model for improvement and providing means for operationalizing quality management (Flynn & Brooke 2001). The criteria of the model are most used as a source of information on achieving business excellence (Bemowski & Stratton 1995). The MBNQA criteria embrace following core values: systems perspective, visionary leadership, customer-focused excellence, valuing people, organizational learning and agility, focus on success, managing for innovation, management by fact, societal responsibility, ethics and transparency and delivering value and results (Baldrige Performance Excellence Program 2015).

The Deming Application Prize was established in 1951 in honour of Dr W. E. Deming and his friendship and achievements in industrial quality (Dale et al. 2009). The model encourages customized TQM implementations on case-by-case basis, rather than following a set model (JUSE 2015). The model consists of ten evaluation categories, with six to 12 sub-categories. The main categories include policies, organization, information, standardization, human resources development and utilization, quality assurance activities, maintenance/control activities, improvement, effects and future plans (Dale et al. 2009)

Self-assessment helps organizations to plan their next actions by giving a comprehensive and systematic review of organization's activities and results, that help

to identify the current strengths and areas of improvement (Dubey 2016). Dale et al. (2009) categorize the benefits of self-assessment process into *immediate, long-term* and *TQM supportive* aspects, described in table 7.

Table 7. The benefits of self-assessment process (adapted from Dale et al. 2009)

Category	**Benefits**
Immediate	• Guides benchmarking • Drives continuous improvement • Encourages employee involvement • Creates visibility for direction • Raises quality awareness and understanding • Creates a common approach to improvement • Can be used as a marketing strategy, raising the profile of the organization • Creation of people-friendly business plans
Long-term	• Helps to keep the costs down • Enhances business results • Balances investments (both short- and long-term) • Creates a disciplined approach to business planning • A holistic approach to quality • Increases the ability to meet customer's expectations • Creating a link between customers and suppliers
Supporting TQM	• Refocuses employees' attention to quality • Health checking processes and operations • Highlights a focus on processes and not just on the end-product • Drives improvements in performance

2.5.3 Quality audit

ISO defines auditing as a "systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled." (ISO 2015). Quality audits are defined as a three-part process, that involves checking (1) the suitability of the planned quality procedures against the stated objectives, (2) the conformity of the quality activities and plans and (3) the effectiveness of the activities to achieve the stated objectives (Woodhouse 2003). Quality audits are systematic and independent examinations to see if activities are performed in accordance with the requirements of the QMS standard of the industry and the internal quality requirements of the organization, which are specified in the QMS documentation. The audits can be internal or external in nature and are divided into four main types:

- Process audit – Audit of a process against its documented description. If the process is undocumented, the audit is done against the responsible management person's description of the process.
- Product audit – Auditing of a product against specifications.
- Project audit – Audit against project requirements and project plans.
- Internal quality audit – An audit performed by qualified employees from the organization with quality auditor training and adequate experience and expertise in the audited areas. (Nanda 2005)

2.6 Productization

2.6.1 Product

Product is defined as a planned and manufactured result of production, that is offered to the market to satisfy a customer need or demand (Kotler & Armstrong 2010) or a thing that is made to be sold (Cambridge Online Dictionary 2019). Products can be divided into tangible and intangible products, consisting of hardware (HW), software (SW) and service or a combination of them (Tolonen et al. 2015, Härkönen et al. 2015), also documentation and know-how can be defined as products (Kropsu-Vehkaperä 2012). Recently companies have begun providing a product type called solutions, which is a type of product that combines physical goods and services (Baines et al. 2009, Gebauer et al. 2005). Manufactured products can be sold from a business to another business (B2B) or from a business to a consumer (B2C) (Haines 2009). All company's products together form the company's product portfolio (Cooper et al. 1999).

2.6.2 Productization and product structure concepts

In existing literature, productization lacks a clear definition and only gives the reader an idea of the context of its use. For example, productization is considered as:

- a product release process in software development context (Rautiainen et al. 2003)

- standardizing non-unique parts of a service and using them on new service projects (Vaattovaara et al. 2007)
- a standardized process aiming to produce high quality product or service that is viable in the market from produced information (Suominen et al. 2008)
- transforming unique service-intensive customer projects into standardized mass market products (Alajoutsijärvi et al. 2000)
- an innovation process, transforming ideas to the form of a sellable product concepts (Tiensuu 2005)
- "standardization of elements in the offering" (Hietala et al. 2004)
- "the degree of standardization" (Lassila et al. 2006)
- a process of analysing customer needs, defining the offering commercially and technically so that the efficiency of the productization can be repeated and the offering is possible to understand (Harkonen et al. 2018b)

Productization benefits the company's new product development (NPD) projects by adding value through dynamic capability of utilizing organization's cross-functional resources early in the NPD phase. It is argued that product development process is just a part of the productization process, indicating that productization is more than just an NPD activity. (Suominen et al. 2009) The productization logic can be also used to support product data, business process and IT system considerations (Silvola et al. 2019). Productization is strongly related to the product structure concept, which allows different types of products to be productized by using similar logic (Lahtinen et al. 2019). According to Harkonen et al. (2015) & Harkonen et al. (2017), a consistent and standardised product structure is a result of the productization process.

The product structure concept is utilized in productization by dividing the product portfolio into commercial and technical portfolio sections and to relevant hierarchical levels inside these sections, which are illustrated in figure 15 (Tolonen et al. 2014, Harkonen et al. 2017). Items in the commercial side can be given a price and are usually visible to the customer. In commercial section, solution level represents the highest level of the product structure, including several product families, configurations of different branches of product structure or single sales items. Product families are on the level below solutions and includes a collection of product configurations. The product configurations include predesigned sales items, which are combined to create unique

product configurations to satisfy specific customer needs. Sales items, on the lowest level of the commercial portfolio are items that can be sold, delivered, and invoiced. They can be hardware, software, service, or documentation items. (Lahtinen et al. 2019) The commercial side of the product structure is linked to revenues and technical side of the product structure is linked to generated costs (Hannila et al. 2019), creating foundations for a company to realize which of its products are profitable and which are not, as the key to product level profitability lies between the sales price of sales item and the related costs of the version item on the technical side (Lahtinen et al. 2019).

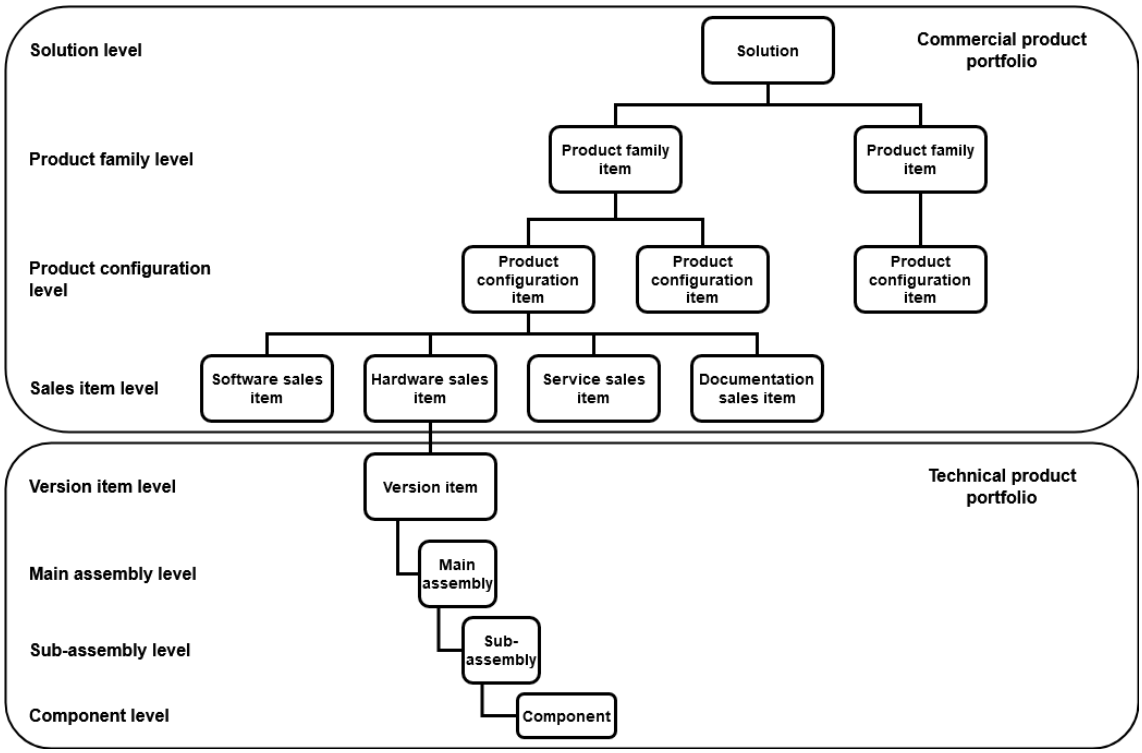

Figure 15: Product structure example (modified from Tolonen et al. 2014, Tolonen 2016).

The technical side includes the technical composition of products as the bill of materials (BOM) and is understood better than commercial side by companies. Productization logic allows to understand the costs of each product version, which is linked to sales item on the commercial side. Version items are created when a part of the original product is improved or changed, usually to reduce costs or to improve quality or performance, replacing the previous version. Below the version item is the technical composition of products. (Lahtinen et al. 2019)

The hierarchical levels of product structure allow assessing modularity (Salvador 2007), which allows maintaining the external variety required by customers and at the same time reducing the internal variety within the company (Krause et al. 2013). The product modularity resides in the technical side of the portfolio (Lahtinen et al. 2019). A clear product structure also benefits the company by illustrating all product related information (Saaskvuori & Immonen 2008), helping to form data models and configuration tools (Forza & Salvador 2006, Kropsu-Vehkapera & Haapasalo 2011), unifying the conception of the product (Harkonen et al. 2017, Tolonen 2016, Kropsu-Vehkapera & Haapasalo 2011), benefiting product portfolio management over lifecycle (Lahtinen et al. 2019) and enhancing the communication and reporting between organizational groups (Harkonen et al. 2017, Tolonen 2016, Kropsu-Vehkapera 2012). Productization aims to maximize the customer benefits and company profitability by increased quality and productivity (Jaakola et al. 2009). Productization makes product scalability, efficiency and fulfilling customer requirements systematic. (Harkonen et al. 2015)

2.7 Product development

In existing literature, product development is defined as:

- "*Set of activities beginning with the perception of a market opportunity and ending in the production, sale, and delivery of the product*" (Ulrich & Eppinger 2008).
- "*Transformation of market opportunity into a product available for sale"* (Krishnan & Ulrich 2001).
- "*The overall process of strategy, organization, concept generation, product and marketing plan creation and evaluation, and commercialization of a new product"* (Kahn et al. 2013).

Product development (PD) has a strong relation to company's business idea and the satisfaction of the market's needs. The main purpose of PD is to enable a company to develop its business idea through the creation of new products or eliminating products that have lost their ability to compete in the market. (Rissanen 2002) Nowadays the

lifecycle of products is shorter than previously, which highlights the importance of PD and creates the need for a steadier PD (Cooper 2000). The significance of new product development has grown dramatically over the last decades and is now the most important driver of competition in many industries (Schilling & Hill 1998).

Product development time, speed and reduction of cycle time have been a popular topic in product development literature (Booz & Hamilton 1982). It is stated, that as the time used to design a product increases, the increased value of the design decreases correspondingly. Therefore, the diminishing return from the design process has to be managed, while balancing the design resolution adequacy and documentation to minimize the production risks. (Oakland 2014) Speed in product development increases the company's ability to respond quickly to changing markets and technologies, increases profitability and can lead to increased competitive advantage by being "first in" to the market. In a study conducted by Cooper and Kleinschmidt (1994) three most important drivers for improving project timelines were defined as:

1. *Project organization* – A cross-functional team working on the project from beginning to the end, led by a strong leader/champion, supported by top management was found to be the most important driver for improved project timelines.
2. *Up-front homework* – The study found that putting time and effort on the up-front homework/pre-development tasks saved time later in the development process. The tasks in question included initial screening, preliminary technical and market assessments, and financial measures, such as detailed market studies and business analysis. These activities are important in defining the product as well as justifying the project.
3. *A strong market orientation* – Projects with proficient execution of marketing tasks were found to be more time efficient and to stay on schedule. Marketing tasks considered in the study are preliminary assessment of the market, detailed market studies and research, customer tests of the product, test market/trial sell and market launch. The quality of the execution of these tasks seems to pay off and cutting corners on them often heightens the odds of failure and is not saving any time on the product development process. (Cooper & Kleinschmidt 1994)

2.7.1 Quality in product development

A well-defined development process supports company's quality assurance functions by specifying the phases of a development project and related checkpoints. Well established phases and checkpoints are one way to ensure the quality of the resulting product. Good documentation practices and ongoing review of the company's development process can also clarify opportunities for improvement. (Ulrich & Eppinger 2012) The design process of systems, processes, products, and services is an important aspect in developing quality into products. The goal of designing quality products is to achieve fitness for purpose and continuously adapt to changing needs of the customers. The design process is important for applying cross-functional communication across the supply-chain and designing the products and services so that customer satisfaction is maximised. (Oakland 2014)

Frameworks, such as the "house of quality" of the quality function deployment (QFD) design management approach are developed for designing products and services according to customer requirements. The QFD approach involves a team consisting of people with different skills in the product design process to identify customers, their needs and to turn the needs into product requirements for different development stages. (Oakland 2014) QFD ensures the integration of customer requirements into new products early in the development process. QFD help organizations move from "we know what the customer wants" to "let us hear the voice of customer" mentality. QFD allows the organization to be more proactive in terms of quality problems, instead of hearing complaints from the customers. QFD helps defining three important factors for product development: who the customer is, what the customer wants and how to fulfil the customer needs. (Zairi & Youssef 2009)

2.7.2 Product development processes

Ulrich & Eppinger (2012) define product development process as "*the sequence of steps or activities that an enterprise employs to conceive, design, and commercialize a product."* This chapter explains the steps of product development process, according to three general models presented in the existing literature.

The Booz, Allen & Hamilton (BAH) model

New product development models are often based on a similar process framework, also known as the BAH model (Bhuiyan 2011). The model is applicable to both new service and new product development (Trott 2008) and has been the foundation for most other NPD systems that have been developed. The model includes all the basic stages of product development models in literature. (Bhuiyan 2011) The model's process stages include new product development strategy, idea generation, screening and evaluation, business analysis, development, testing, and commercialization (Booz & Hamilton 1982). The NPD stages are presented in figure 16.

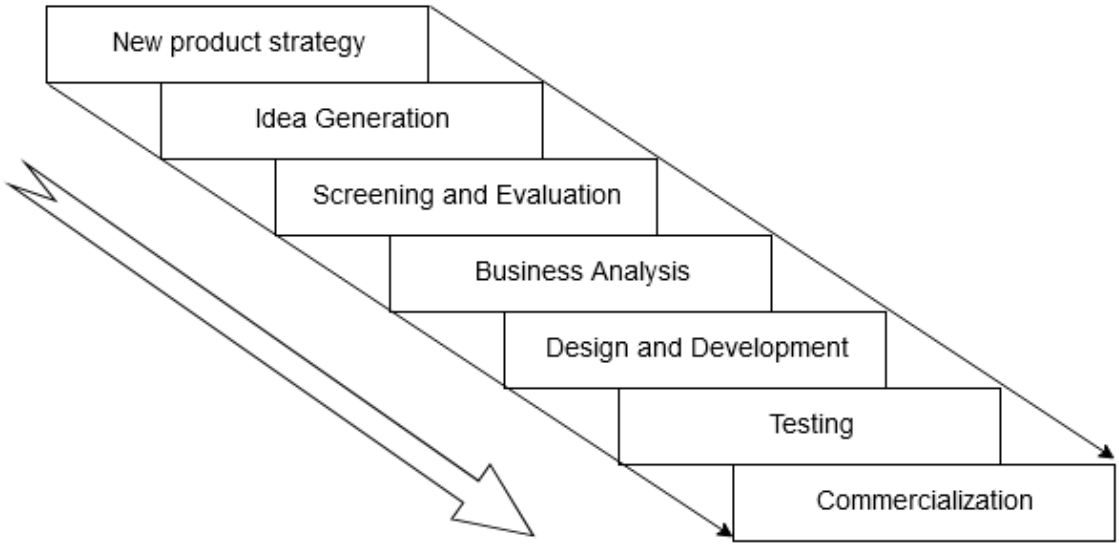

Figure 16. The NPD process stages of the BAH model (modified from Booz & Hamilton 1982).

The generic product development process

Ulrich & Eppinger (2012) present a generic product development process consisting of six phases: planning, concept development, system level design, detailed design, testing and refinement, production ramp-up. Next, the development phases are described more closely:

- *The planning stage*, often referred as "phase zero", links the development process to advanced research and advanced development activities. The project's mission statement is the output of the planning phase, which is required to initiate the concept development and guides the development team.
- *The concept development* phase aims to generate alternative product concepts based on the identified needs of the customer and establishing target specifications. A concept describes the form, function and features of a product. Usually, a set of specifications, a competitive products analysis and economic justification for the project are presented with the concept.
- *The system-level design* phase provides definition for the product architecture, decomposition of the product into subsystems and components and preliminary design. Plans for the production system and final assembly are created.
- *The detail design* phase involves the specifications for geometry, materials and tolerances to all unique parts of the product, as well as identification of standard parts to be sourced from suppliers. A process plan and manufacturing tools are developed for the product parts. Control documentation is obtained as the output of the detail design phase, describing the geometry, tooling, manufacturing process plans and assembly of the product. In detail design phase, three critical issues of the product development process are finalized: materials selection, production cost, robust performance.
- In *the testing and refinement* phase multiple preproduction versions of the product are constructed and evaluated. Early constructed (alpha) prototypes are built with production-intent parts, without the actual production processes, aiming to clarify whether the product works as designed and how it satisfies the key customer needs. Later (beta) prototypes consist of product parts that are manufactured according to intended production processes but may not be assembled according to the final intended assembly process. Beta prototypes are evaluated internally and often tested by customers, to gain performance and reliability information of the product, which can be used further to identify required engineering changes to the final product.
- The final *production ramp-up* phase includes the manufacturing of the product using the intended production system, training workforce and solving the remaining problems within the production processes. Products produced in the

ramp-up phase may be supplied to specific customers and any remaining flaws are identified. The production ramp-up phase moves gradually towards ongoing production. Launch of the product happens at some point of the transition and the product is ready for widespread distribution. Shortly after launch, a postlaunch review can be arranged, including a project assessment from both commercial and technical point of views, and discovering viable improvement opportunities for future projects. (Ulrich & Eppinger 2012)

The Stage-Gate process

Another tool for managing NPD processes is the stage-gate system, that is used in many well-managed companies, such as P&G, 3M and ITT. Stage-Gate system is a business process built for speed, with activities occurring in parallel across different functional areas within the firm. (Cooper 2008) A stage-gate system manages innovation process by dividing it into predetermined stages and gates, each stage consisting of different related cross-functional activities (Cooper 1990).

A stage involves a project team working, obtaining information, and integrating and analyzing collected data in a looping, iterative and back-and-forth manner. The project team collects deliverables to the decision point. The deliverables are decided at the output of the previous gate and are based on a standard menu for each gate. A deliverable can be the results of a set of completed activities, for example. A stage is followed by a gate, where go/kill decisions are made for further project investment based on the results of integrated analysis and criteria on which the project is judged. The principle of a stage-gate is illustrated in figure 4. (Cooper 2008) A gate works like a quality control checkpoint in production process, including a set of inputs, exit criteria and an output. Project leader brings the inputs to the gate where they are judged upon the set criteria. Each gate is managed by senior managers that act like “gatekeepers”, having authority to approve the resources for the project. Outputs of gate meetings are typically Go/Kill/Hold/Recycle decisions along with action plan approval for the next stage. (Cooper 1990)

A typical stage-gate model includes four to seven gates, depending on the company or division. (Cooper 1990) Each stage costs more than the preceding one, but at the same time the unknowns and uncertainties are driven down, thus risk is effectively managed. The typical Stage-Gate system for major projects and next generation Stage-Gate models for moderate risk (Stage-Gate XPress) and minor change projects (Stage-Gate Lite) are presented in figure 17 (Cooper 2008).

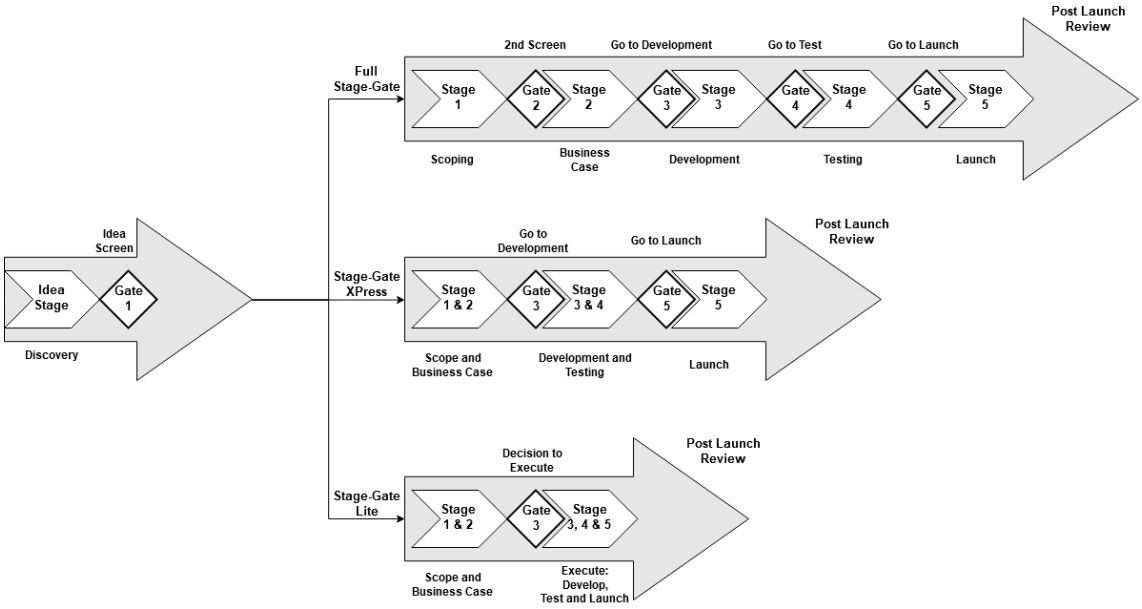

Figure 17. The typical and next generation Stage-Gate models (modified from Cooper 2008).

2.8 Literature synthesis

The literature review covers several areas regarding QM and its role and benefits in today's organizations. Table 8 summarizes the main points of topics discussed in the literature review. Theory key points regarding the next research chapter, the current state analysis, are also defined and presented.

Table 8. Key points of discussed topics in existing literature

Topic	**Existing literature key points**
Quality	Quality is understood from several viewpoints. In a business world, a common perception of product or service quality is related to meeting the requirements of the

	customer. Another take on quality is "fitness for use", that is further divided into quality of design and quality of conformance. The customer satisfaction level and meeting the applicable specifications are considered as the most important indicators of quality. In a purely technical view, quality is understood as being proportional to variability; when variability in product's features decreases, quality increases, leading to less deficiencies and therefore increasing ability to satisfy the stated or implied needs. In today's world, quality is seen as one of the most important decision factors for customers and therefore is seen important for both small and large manufacturing and service organizations.
Quality management	Quality management is a strategic tool involving activities that are required to plan for quality and to satisfy quality objectives. Quality management focuses on organization's socio-technical system, promoting internal (teamwork and autonomy) and external (cooperation with suppliers and customers) social aspects. Quality management involves quality planning, quality control, quality assurance and quality improvement activities. Over time, quality management has evolved from detective operation (inspection and quality control) to preventive (quality assurance and total quality management).
Process management	Managing and improving processes is a widely accepted way to improve quality of products and services. Process management enables an analytical view on organization's processes to ensure that critical activities affecting customer satisfaction are optimized. Process management also helps assessing the performance of individual processes and understanding the flow of information and resources within the organization.
Performance measurement	Measuring organizational performance is one of the main principles of total quality management. On top-level, measurements help the organization track its' progress towards goals and identify improvement opportunities. On process-level, tracking the critical process steps of key processes helps to meet customer requirements, prevent errors, reduce variability, improve cycle-time and improve productivity. The top-level metrics are defined as key performance indicators, which are supported by lower level performance metrics.
Quality management system	A quality management system aims to achieve the quality objectives of the quality policy and customer and internal requirements by managing human, administrative and technical factors that influence quality. A QMS works as a framework of reference points, ensuring that organization's processes work with the same information, skills and controls. The seven QM principles defined by ISO form a basis for requirements for QMS certification, describing the minimum requirements and essential elements for a standardized QA system. A QMS must be audited regularly to ensure its adequacy.
QM benefits	QM benefits both large and small companies by systematizing their operation,

and adoption	considering both social and technical aspects of an organization. QM practices have been used to improve organizational performance, increase product or service quality and enhance internal and external cooperation. QM has been in the business for a long time, but its adaptation in SMEs is rather limited, due to lack of human resources or adequate support from top management. Adapting QM principles in a company can help to change the organizational philosophy from problem detection to problem prevention, thus elevating company's maturity level.
Product	Product is defined as a planned and manufactured result of production. A product aims to satisfy a customer need or demand. A product can be tangible or intangible and consist of hardware, software, know-how or document elements, or a combination of them. A solution is a product type combining physical goods and services. Products can be sold from a business to another business or from a business to a customer.
Productization	Productization is a cross-functional process of analyzing customer needs and defining the offering both commercially and technically. Standardized productization process aims to increase efficiency and make the offering and conception of the product easier to understand. Productization benefits the organization by enabling a consistent and standardized product structure, adding value in NPD projects, supporting product data, business process and IT system considerations, assessing modularity and benefitting product portfolio management (PPM) over lifecycle. A well-developed productization process supports company's QM functions by systematizing product or service creation and management during its lifecycle. The systematic approach for defining products and services fits together with the process approach emphasized by QMS standards.
Product development	Product development allows a company to create new products or eliminate existing ones to support the company's business idea and satisfy the market's needs. In a quality management context, product development process has an important role in assuring and controlling the quality of resulting product or service. Several different product development processes are used by different companies, based on the needs and preferences of an organization. The BAH model is considered as the basis for all product development process models, such as the Stage-Gate model that focuses on development speed.

The existing literature about productization and QM gives a fundamental base for studying the current state of the case company. Some of the literature subjects can be summarized as key points on which the current state analysis is based on. The key concepts of theory, that are utilized in the current state analysis:

1. **The QM evolution** chart by Dale et al. (2009) and the characteristics of each QM evolution level can be used to analyze the case company's current QM maturity. The QM evolution levels cover quality management practices from inspection to TQM, describing QM practices and the degree of their implementation from detective to preventive operation. The progression model helps to bring the best practices from the benchmarking survey to the literature context and understand differences between examined companies and the case company. Other authors provide more insight into QC, QA, and TQM and into what must be implemented and realized to achieve these levels of QM in an organization.
2. Quality must be planned into products and services. On top-level, **quality planning** helps the organization to turn its quality policy into measurable short- and long-term quality improvement objectives. Quality planning supports both QC and QA elements and helps defining the structure, documentation, and scope of a QMS. Quality planning helps translating the voice of the customer into requirements, and thus defining quality requirements for processes, products, and services.
3. **Continuous improvement** should be a regular part of improving quality. The focus of quality improvement activities should be on improving processes and thus improving products' and services' ability to meet requirements.
4. Effective quality management requires **top-management support**. The top management is responsible for bringing the quality policy and objectives to everyone in the organization and supporting implementation and review of the QMS. Self-assessment methods can be an effective managerial tool, guiding the organization's improvement process. It is crucial that the whole organization participates in QM and that the organizational culture is conductive to creating high quality products and services.

3 CURRENT STATE ANALYSIS

3.1 Case company description

The case company in this study is a small high-tech company that operates in hospital, care homes and home care business segments, providing health care security and communication solutions in Finland and Sweden. The company is the leading manufacturer of Bluetooth Low Energy RFID and cloud technology-based solutions for healthcare and communication. The company's product offering includes solutions for personal security, nurse calls, access management, communication and location services. The products consist of hardware, software and service elements. Used technologies in products include i.e. 2G, 3G, 4G, Bluetooth, GSM, sensors and IoT. Collected data from products is directed to company's own cloud service to provide services 24/7 to their customers. The products can be sourced from subcontractors and/or assembled internally in the company, depending on the nature and production volumes of the product. HW products are designed in the company or by using subcontractors. Electrical and software designs are developed in the company. A large portion of sales is handled through resale agreements with various companies.

3.2 Research method

Because of the complex nature of the studied issues and the objective of creating practical models and tools for the case company, a qualitative research method was used to analyse the case company's practices. Several internal semi-structured interviews were carried out in the case company, numerical data was gathered from company's internal system and three other companies were interviewed semi-structurally for benchmarking purposes. The gathered data was then analysed and put into more formal format. The study was carried out as a qualitative analysis of the case company and it was done by using a constructive research method, which belongs to a wider group of case study research methods (Lukka 2001). The elements of constructive research are presented in figure 18.

Figure 18. Elements of constructive research (modified from Kasanen et al. 1993)

3.2.1 Internal interviews

First, the internal interviews regarding productization were arranged to assess the current productization process and its influence on product quality. The interview questionnaire consisted of 19 questions to examine the current state of productization and related problems in the company. The interview was semi-structured in nature to allow free discussion about the topic. Notes were written down during the meeting. The interview questionnaire is presented in Appendix 1. From the company, five people participated in the interview, including:

- Two product managers
- Operations manager
- R & D manager
- After sales director

A total of 20 people working at 9Solutions were interviewed individually for the quality section. The goal of these interviews was to investigate the current state of quality management in the company and clarify the quality related challenges and problems that exist in the products and within the organization itself. The interviewees were chosen from different departments and functions of the company and from all levels of the organization, from production workers to top management. The wide variety of interviewees provided a comprehensive overview of the current QM practices and quality related challenges within the company. The interview group consisted of:

- CEO
- CFO

- Marketing director
- Sales director
- Two product managers
- Customer success manager
- R & D manager
- Two test engineers
- System specialist
- Deployment manager
- Customer success specialist
- Operations supervisor
- Operations manager
- Assistant operations supervisor
- Four people wished to stay anonymous

The interviews were semi-structured and based on 43 questions (Appendix 2). Nine extra questions were presented to members of the management team. The interview was designed based on the literature review of quality management and divided into four sections: *background, quality issues in the company, examining existing performance* and *requirements for quality management system*, which was only discussed with the members of the management team. All interviews were conducted in Finnish and recorded. A single interview lasted from 20 minutes to one and a half hours. The answers were collected to an excel file and combined into key findings.

3.2.2 Benchmarking

Examining other companies' QM procedures is perceived as a valuable opportunity to get ideas and discover the best practices of QM in SMEs. The approached companies were chosen because they are certified for quality, approximately same size as the case company, their products share similarities with the case company's products (hardware, software and service aspects) and they preferably have a long history operating in their field.

Three local companies were asked for a benchmarking survey to understand the best practices in building quality into products and managing quality in an organization. The

themes, content and goals of the questionnaire were discussed in the case company beforehand. Quality representatives were individually interviewed from each of the benchmarking companies and their organizational roles included quality manager (company A), VP of technology (company B) and sales director (company C). The interview results were analysed and compared to identify improvement opportunities. The interviews were held in Finnish and lasted about one hour. The summary of the interview results is presented in appendix 4. The benchmarking companies are operating in following industries:

- Company A: Measuring devices and research equipment (30 employees)
- Company B: Applications and software (100 employees)
- Company C: Access control and access control devices (40 employees)

The interviews turned out to be a useful method to get a realistic view on how companies have implemented and utilized a QMS and QM practices within their organizations. The benchmarking interview questionnaire is presented in Appendix 3.

3.3 Current state analysis of the case company

In this chapter, the case company is analyzed according to the findings of the literature review. Productization chapter describes the current productization process in the company, the problems associated with the process and how product structure, product lifecycle and product portfolio concepts are applied. Specific product development chapter describes the current state of the NPD process. In existing literature PD is viewed as a part of productization process, and thus the challenges identified in case company's NPD also apply in productization context.

The current state of QM chapter identifies the level of QM adaptation in the case company and common challenges in managing the quality of their products. Current level of QM at 9Solutions is analyzed by analyzing the existing QM elements and comparing them against the characteristics of different maturity levels presented in the literature review. The interviews also consider how quality culture has been developed

at 9Solutions, by examining the understanding of top-level policies and their adoption among the interviewed employees.

3.3.1 Productization and product structure

In the case company, products are made for two reasons: a market pull or a technology push. In a market pull situation customer demands stand out from the market and product is then developed to fulfil the need. This is a common way for case company's product to be born, since the requirements are well known from the beginning. In a technology push situation, a new product is developed in the means of increasing the turnover, and product is brought to market without an existing specific customer demand. Modularity is used as much as possible in the company's products to reduce workload and make product processes more efficient, for example the same circuit boards and Bluetooth equipment are used in multiple products. Productization plays a large role in the company's way of bringing products to the market. The productization process flow is defined on the top level, including life cycle stages for the product from the innovation phase to maintenance phase. Productization milestone gates act as the gates for product development. Life cycle phases are not defined beyond product maintenance phase in the 9SPLC productization process. The custom Stage-Gate process is illustrated in figure 19.

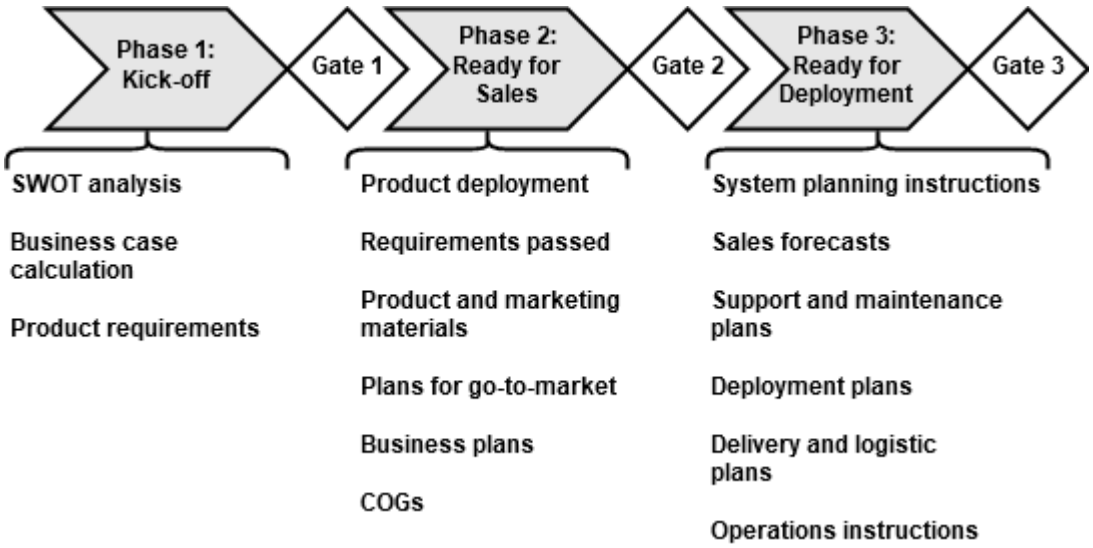

Figure 19: Productization process phases and included activities and outcomes in the case company (9SPLC)

The case company's customers are divided into three market segments: hospitals, home care and care homes. The products are divided among these three segments, but there is no conscious division to further product subcategories or product families. Processes do not support the commercial productization, including market segments, product families etc. The products are sold as configurations, usually including hardware and software aspects, as well as possible installation and maintenance work. Some products are included in bundle deals, which include multiple configurations, and are usually made as customized work for a specific customer. These bundles are added to company's product portfolio along with all other products and bundles, that leads to "ghost products" which clutter the portfolio. For example, at the time of the interview, the company's portfolio included spare parts for products that do not exist anymore. On the other hand, there are products that must exist in the portfolio for the company to participate in the public tenders of the healthcare industry. Currently there is no conscious effort to remove unnecessary products from the portfolio, and they tend to remain in the maintain phase.

3.3.2 Challenges in product development

The NPD projects in the company are done with a customized stage-gate model. Currently used stage-gate model is a plainer version of an earlier one, which was seen too complicated, time and resource consuming process. The process used to include nine gates, but the amount has been reduced to three. The set gates and the related milestone checklists are often ignored to hurry a product or feature. The same process is used for product variants, and the only difference is skipping some stages if necessary. The interviewees stated that the NPD situation is often unclear and how many products were under development, when they were supposed to be brought to markets and who had responsibility over it. Sales is hesitant if the product can be sold yet to the customer, or which features a future product will have. Roadmap view of upcoming projects have been brought up to sales personnel to combat the issue. However, the roadmap found in the company's internal system has not been updated for several months at the time of writing this thesis.

A significant problem regarding NPD in the company is time pressure. It is present on most of projects and there is not enough time or resources to be allocated on all projects.

New products are brought to market carelessly, without a proper ramp-up phase or proper internal informing. During the interview, a "bypass lane" in product development process was brought up, through which some new projects just pop up and are suddenly in the development and soon on the market. The bypass lanes are managed by company's top management and the ideas do not have to be calculated and verified, compared to the projects emerging through conventional R&D route. Systematic and objective evaluation of new product ideas seems to be lacking.

Challenges in product development at 9Solutions can be summarized:

- Lack of structure and documentation in the NPD process
- Milestone reviews are usually ignored in hurry
- Lack of internal communication about products under development
- No objective evaluation of new product ideas

3.3.3 Current state of quality management

For large portion of participated interviewees, quality equals to customer experience and fulfilling the needs of a customer quickly. Also, robustness and conformity to specifications are important aspects of quality among the interviewees. According to the interviews, the main quality management related problems in the company are challenges in schedule which leads to hurry in processes throughout the organization, insufficient testing of the products, challenges in software bug prioritization, and too much new products to be developed and launched, leading to poor manageability. Also, weak product quality of contract manufacturers is mentioned by several interviewees. Quality management is missing on many areas of organization and there is no person to focus on and take responsibility over quality. "Currently everyone is in charge of quality, thus no-one is", stated one interviewee. The level of product quality was seen varied. A couple of interviewees stated that product quality is currently at a good or excellent level, while others saw it as weak. The common opinion was that quality management has been improving during the last year, due to documentation requirements from the factories and introduction of the improved documentation management. 9Solutions also has ISO 27001 certification, which covers a part of the required documentation procedures.

Overall, the company can be seen to operate in reactive state, “fighting fires” that are caused by hurry, inadequate documentation, planning and testing of both software and hardware aspects of products. Customers are sometimes promised to get features in a too small timeframe, with penalties if the agreed point of time is exceeded. Some of the new products and features are launched incomplete or even without testing. Current way of working causes too much resources to be allocated to fix problems that arise after the products have reached customers. Faulty products returning from the customer employ support team and technicians and the product itself leads to extra costs for the firm. Sales organization, as well as resellers, can be hesitant to sell new products if there has been issues recently. Problems in product quality can also affect the reputation of the company, which is hard to regain if lost. In the worst-case scenario, the customer switches to another company. On the other hand, agile product development of minimum viable products (MVP) and ability to respond to customer needs quickly has been one of the cornerstones of the company’s success and ability to gain market share so far. Currently, the company has begun operating abroad, so a more structured way of managing quality is required.

Inspection and QC

For quality control purposes, 9Solutions has implemented several procedures. Operations department carries out random sample inspection tests and out-of-box reviews for some of the products, as well as production testing on a test bench for some products, before their dispatch. New software releases are tested in R&D department and reviewed before their release. Quality manual creation according to ISO 9001 standards has been started earlier in the company, but it has never been finished. Product related documents are stored in Google Drive. A new product data management (PDM) system has also been introduced to make the control of products’ bill of materials (BOM) and other product related documents easier. The PDM system is available only for a couple of persons in the company due to limited number of licences.

Faulty products and customer returns are handled through a well-established return merchandise authorization (RMA) process, which starts at support department. The customers contact company’s support team by calling or e-mail, the team then handles

the issues with help from operations and/or R&D departments if needed. The amount of customer returns is reviewed once a month. An annual group hoshin plan is used to implement long term enhancements to different organizational functions. Improvement areas focus on topics such as improving supply chain operations, logistics costs optimization, customer experience, communications development and R&D quality improvement. In the end of the year, many of these topics are on track, and several points are still on far behind status.

A few metrics are in use to measure different quality-related aspects of the firm's operation. Financial metrics, such as warranty costs originating from customer returns, and customer surveys are well established and the main tools to evaluate improvement in the organization. Every two months RMA inventory is held to review the number of returned products. A maturity grid is in use for individual products. It represents a maturity stage to evaluate key product's market readiness and shows current bugs present in the product. The bugs are categorized into different risk groups with weight coefficients. For software, the metrics in use include the measuring of number of bugs present in a product or in the system, and a tool to evaluate the bugs priority from critical to low. The software bug prioritization is seen as an opportunity for improvement.

Quality aspects in product development are considered inherently, based on knowledge and experience of senior designers. Review meetings for software are held in R&D, but a standardized way of including quality aspects into development process and reviewing them systematically during the process is missing. Certain quality targets are set with product requirement specification, but other aspects of quality planning are not included in the development process. According to an interviewee, quality planning is present only at the product development phase, and it should be covering the whole service chain as well. More time for developing product specifications is required, stated an interviewee.

Testing processes are being improved continuously by the personnel working in testing on R&D. Steps have been made to make products more physically robust and new physical testing methods have been implemented in production recently. Testing of both

software and hardware is still seen incomplete in both operations dep. and in product development, according to the interviewees. Launched products are tested with a flasher tool to check the basic functionalities of a product in operations department. An interviewee stated that products are not designed to be tested, therefore the production test methods are often unable to find faults in products. The structures for systematic testing in production are missing. Personnel working in operations department are wishing for own test methods and procedures for individual products. The software releases are tested by two persons, who were both included in the interviews. According to the interviewees, testing of the cloud service and software releases should be done more systematically and extensively, so that every features' main functionalities are tested. Currently there is not enough time and human resources for throughout testing of a software release. A systematic requirement log for software development test planning is being implemented, however.

QA

Documentation of current elements of a quality system and procedures is done partly in the company. It was stated by an interviewee that the processes in the company are known by everyone by default, but they are not written down anywhere, other than ISO 27001 related processes, procedures and requirements, which are all well documented. One interviewee stated that the specifications of some products are missing, which makes test planning difficult. Testing related documentation is seen to be on a good level. A quality improvement plan has been created for R&D department, covering QA testing process based on use cases and product requirements, but it has not been put into practice.

When it comes to finding the causes for faulty features and products, there is consensus that the root causes are usually well investigated. Some of the software bugs cannot be duplicated, as the information regarding the issue might be incomplete. On hardware side, the products can be traced back to the manufacturing week and manufacturer of the product. Some of the used components can be traced back to the manufacturer. Operations maintains a database of delivered products and their current location, based

on the individual ID number of each product. This database is said to be used frequently when resolving reclamation issues.

Statistical methods are not present in the current state of quality management. Costs of quality are defined as warranty costs, which are considered as requirements for bonuses for some personnel. The case company's annual RMA costs per sales have quadrupled during the last few years. Business development is measured in detail and reported to board of directors quarterly. KPIs are also defined for information security, on top of financial measures. Response time to customer complaints within 24 h is defined as an agreed KPI in the quality manual. Systematic process of defining metrics and KPIs to measure improvement is not present.

TQM

Top level quality policy and objectives have been developed earlier at 9Solutions and defined in the quality manual. The policy and objectives are presented in figure 20. As described in the existing literature, the quality objectives should derive from the quality policy, which demonstrates that 9Solutions has approached the QMS with the right attitude in the past. However, since the quality policy and objectives have been updated several years ago, updating them would be beneficial if a QMS was to be implemented.

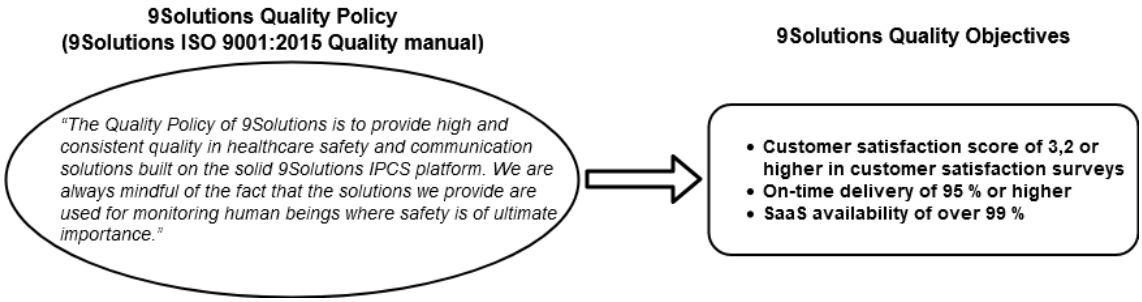

Figure 20. The current quality policy and objectives at 9Solutions.

Spreading and adopting the company's strategic message and creating and maintaining quality culture in the organization is considered challenging, according to an interviewee. Another interviewee stated that quality and customer experience do not play any major role in weekly management culture. Innovation and innovation through

teamwork is often hindered by copious amount of work. The management is seen to have the ambition to maintain a culture of excellence within the organization, but the real-life challenges and promises to customers lead to products being delivered to customers too early. A defined, transparent and manageable process for working with a "forward slanted" mentality as a company and taking customer feedback into account at the same time is seen necessary. A process view that clarifies the way of working to all people in the organization is needed. Strategic targets are specified for the organization and the beforementioned quality policy is found in the quality manual. However, only a few interviewees were aware of the existence of the quality manual or quality policy and objectives. Customer satisfaction is one of the most important areas of company's strategy, so quality is considered in that sense.

The organization supports continuous improvement with tools such as top 5 customer voice procedure, problem-centred better together workshops, creating and monitoring big annual targets within the management group, ISO 27001 related risk management procedures and action plans, and the possibility to spend a few hours a week to self-imposed training and self-development besides working. People working in the company has been trained in information security issues. Quality training is not arranged separately in the company, and some interviewees hoped for more extensive introduction to the work, as currently everything must be learned by asking from a person that is familiar with the task. HR measures are also applied, measuring employee well-being quarterly and annually with surveys.

Information between top management and workforce is shared in weekly meetings. In the meetings, the most crucial issues of different departments and upcoming possibilities and challenges are discussed. The meetings are a good way to get "top down" information, according to the interviewees. Horizontal information flow between teams is seen to be restricted. This leads to vital information not being delivered across the organization in timely manner, which can then lead to frustration and demands improvisation when a change in a product or feature is discovered with a customer instead of well beforehand. Information from customer interface may not always reach the management team.

A new process for ideas and proposals is needed, according to an interviewee, current way of making proposals is not in active use. One interviewee points out that the project management software is used within R & D department only, when it should be a transparent tool for the whole organization. The management is seen to dislike the program and therefore refuse to use it. As a result, excel files in Google Docs are used to distribute information, which is seen as an inaccurate and restricted way of doing things. One interviewee stated that people do not always use the information channels, even if they have requested them in the first place. External communication has improved during the last years with defined communication processes. A common language between the company's development engineers and nurses using the product should be found. Similar problem does not exist with the subcontractors, as they are experienced in the field. A proper product launch phase is seen as an opportunity for quality improvement.

3.3.4 Key improvement objectives from the internal interviews

Table 9 provides a summary into findings of different topics in the internal interviews in the company. The table is divided into key themes, the current situation at 9Solutions in that area and improvement objectives. The objectives are a list of the development suggestions for stated issues, based on literature findings and proposals stated by the interviewees.

Table 9. Challenges and improvement objectives from the internal interviews.

Area of challenge	**Current situation**	**Improvement objective**
Productization	• Product structure is not defined on commercial side • Large product portfolio • Communication between users of products and developing engineers, "common language" missing	• Defined product structure • Evaluating the needs of a customer

Product development	• Many ongoing and overlapping projects • Development milestones often ignored in hurry • No systematic and objective review of new product ideas • A "bypass lane" for development projects • Unclear product roadmap • No responsible person (such as project manager) to organize and oversee the development projects • Lacking communication between departments during a development project and at the launch phase • No proper product ramp up phase	• Product idea evaluation model • Resourcing project management • Communication • Review and auditing of development projects • Quality planning procedures
Product quality	• Annual warranty costs per sales have increased fourfold in the last few years • Rework and fixing problems bind resources • Quality problems with suppliers • Sales department is hesitant to sell new products after quality problems	• Increase product quality by implementing QM and a QMS • Establish supplier evaluation
Quality management	• Reactive way of operation • No active quality management • No person to take responsibility over quality issues • No defined quality processes • Too much fixing problems afterwards, after the product has reached customer	• Change the way of operation from reactive to preventive • Establish quality management in the company • Quality targets
Quality control	• Existing metrics consist of number of customer returns and customer tickets, financial metrics, information security related KPIs, number of hotfixes, customer satisfaction surveys, product maturity index • Software bug prioritization • Not enough time for product testing activities	• Define quality objectives and measures
Quality assurance	• No documentation of QMS elements • Processes are known by everyone, lack of process documentation, outdated process documentation • No cross-functional process mapping • Quality manual is unfinished and not in active use • No statistical methods in use for managing quality • Quality costs defined as warranty costs only • No systematic process of defining metrics and KPIs	• Creation and documentation of QMS • Defining processes, process owners, procedures, and work tasks • Quality manual • Statistical methods for QM • Defining CoQ model • Defining quality objectives and KPIs
QMS requirements	• No systematic review of suppliers • No internal quality auditing processes (excluding ISO 27001 related processes) • No systematic way of analyzing collected data	• Supplier review • Internal auditing processes • Quality data collection and analysis

3.4 Best practices from the benchmarking companies

3.4.1 Quality management

The quality management systems and procedures shared many similarities as well as differences in the three interviewed companies. All the visited companies have the ISO 9001:2015 certification, quality is seen as of high importance and invested in, processes and corresponding metrics are defined throughout the whole organization and quality manual acts as a documentation backbone of the system. The companies have defined KPIs and quality targets in use for different organizational functions. All the companies have had their QMS in use for several years, quality is recognized as one of the main functions of the companies, and the systems in use are implemented to work on all organizational levels.

In the beginning of the interviews, meaning of quality for their company was asked. Companies A and B emphasized the importance of precise targets and requirements set for different organizational functions and involving the whole organization in quality work. Company A finds continuous improvement of know-how as a cornerstone of quality in their company. For company C, quality is seen as a tool helping the organization to function better continuously. All the companies perceived their product quality to be currently on a good level and company C sees the achieved good product quality as a reason the company is renowned in their field of business. Interviewee from Company B stated that there is always quality deviation in new products.

All the interviewed companies have one or more persons working on quality-related tasks. Companies A and B include a quality manager, as well as a few persons with the word quality in their job title. Company C had only one person working as quality manager, as their QMS and included processes and procedures have been well established for a long time and current quality management system maintenance work only includes adjusting minor details of the processes and metrics in the quality manual. Quality investments also include ISO 9001-certified and regularly audited QMS in place in all the companies. The ISO quality standard related training has been presented to all employees in company B. The company C pointed out their HR investments to

company's customer support and services to provide better customer experience and service quality, as well as to gain competitive advantage.

The QMSs of the three companies were similar in terms of process hierarchy and their extensive coverage, effecting and supporting the work on different levels of organization. Quality manuals are well structured, updated and utilized throughout the organization in all the studied companies. Usually the person updating and maintaining quality manual related tasks is the quality manager. The interviewees find important that the set processes are followed in order to prevent failures. One interviewee stated that quality problems usually occur after a process or processes have not been followed correctly. In all interviewed companies, every functions' processes and sub-processes, all the way to work instructions, are documented, including the dedicated process owners. Companies B and C have the most extensive use of quality measures, as there was defined and regularly reviewed key performance indicators for every functional group of the organization. The main characteristics of QMSs of the benchmarking companies are described in table 10.

Table 10. The characteristics of the benchmarking companies' QMSs.

Company	**Quality management system**
A	QMS is structured in the form of light memo sheets that are updated continuously. Everyone in the organization participates in continuous improvement and updates the quality memos. The memo practice covers the whole company and is used on all organizational levels and on several functions. Process mapping from key processes and associated sub-processes all the way to work instructions. Precise quality targets in operations.
B	An internal structured database of company's processes, process owners, KPIs, work instructions, testing procedures and milestone checklists. Set requirements and targets for different organizational functions that must be fulfilled to achieve quality. A public action list, that includes future improvements, targets and KPIs and corresponding reviews and audits.
C	Quality manual contains defined processes, metrics, process owners, designated responsibilities, work instructions and audits. "Annual wheel of quality" distributes internal quality themes and reviews around the year.

3.4.2 Quality measures and audits

All the interviewed companies had implemented KPI measurements in several functions of the organization. The most utilized metrics include financial metrics and the number of monthly customer claims and reclamations. Company C has established an annual

customer satisfaction survey through a subcontracting company. The company interviews Company C's customers annually and lets the customers themselves to pick the KPIs and measures that are important to them. Customer satisfaction is measured through these self-set metrics and is seen as a valuable tool to improve communication with customers. Quality performance was measured through several other KPIs in the interviewed companies:

- Product returns (Companies A and B)
- Product service and maintenance (Companies A and B)
- Reliability of delivery (Company B)
- Production yield (Company B)
- Most common defects (Company B)
- Product development milestone schedule (Company B)
- Production capacity (Company B)
- Lead time of product development process (Companies B and C)
- Costs of product development process (Company C)
- Rate of warranty product replacement (Company C)

Reviewing the KPIs and set quality goals are done monthly, quarterly or annually on companies B and C, depending on the nature of the metric. The review methods and schedules of different metrics are defined in the quality processes in the company C. The quality processes are defined in the company's quality manual and include information about the metric; where the information is collected from, how it is collected and where the information is saved. In company B, each organizational function collects the results of their metrics and forwards the results to the quality manager, who coordinates the collection of measurement results. For example, the sales and marketing department collects customer satisfaction data and sends it to the quality manager.

Company B's quality targets form the basis for the performance indicators, so essentially, the company sees quality goals and KPIs strongly connected. Mentioned quality targets include on-time delivery, customer satisfaction and HR metrics, such as employee satisfaction. Company C has set maximum limit for complaints and product

replacements, but the ultimate quality goal of the company is ensuring customer satisfaction, stated the interviewee. Quality targets in company A include improvement of procedures, satisfied customers and the constant growth of know-how.

The internal measuring and auditing processes and procedures are well established in the benchmarking companies. Externally, ISO 9001 certification audits occur annually and on top of that the companies have their own internal audit regimes. The internal audits can be regular or irregular, depending on the nature of the subject. In company A, internal audits are performed as a problem arises in production line or in resulting product. The scope of internal audit can be manufacturing equipment, a process step, a work task or any larger entity. In company C, annual internal audits for every main function are spread around the year according to "the annual wheel of quality." The internal audits focus on one department at once, and the auditor is from different department to provide a neutral view on the auditing. The schedules and checklists for these audits are summarized in an internal audit plan. Action lists act as the follow-up of an audit and specify the necessary improvements or changes to be made. The action list is reviewed in the next annual audit meeting to see if improvements or corrections has been made. Actions are based on measurable facts, not opinions of any individual. Company B uses similar public action list, including improvements to be made and related targets and KPIs to measure the progress. The list is monitored monthly and annually during audit meetings.

The methods for measuring costs of quality varies among the interviewed companies, summarized in table 11. Company A considers quality to be a project among others, and quality is defined as its own cost centre, including corresponding dedicated working hours. In company B, the costs of product maintenance work are considered as the realized quality costs. Company C considers the amount of product replacements as the base for quality costs.

Table 11. Costs of quality measurements in the benchmarking companies

Company	**Cost of quality measurement**
A	Quality as a separate cost centre among other projects, specified amount of dedicated working hours

B	Maintenance costs
C	Product replacement costs

3.4.3 Quality in product development

The product development processes were well established and documented in all benchmarking companies, but the product development process itself differs in each company. Company A uses an iterative prototyping development model with the customer involved on testing of the product and giving feedback. The development process itself includes the following phases: supplier evaluation, risk evaluation, the development itself and qualification for production. In the qualification phase, a review meeting is held with selected people. The project manager is responsible for moving the product from development to production. The developer of the software or product organizes the meetings to review their part of the development. When the software or product is at the end if its lifecycle, the developer writes a one-page manifest about the product, summarizing the crucial information to be archived and used later if needed.

Companies B and C operate with milestone and checklist-based models on their product development. Company B works with six milestones on their development model, with intentions to add a feasibility milestone in the future. Every milestone includes its own process chart and a checklist that is reviewed on physical audits after all functions on the list are completed. Milestones are linked to schedule monitoring, as product development milestone schedule is one of the KPIs of product development. The milestone reviews are hierarchical and split into segments. Programming milestones are on the top level, managed by project manager. The programming milestone partly consists of smaller sub-milestones for different divisions, such as HW, mechanics, production testing and maintenance. The leader of each department or function organizes the audit of sub-milestones. The milestone audits for both top level and smaller milestones, include the related persons and usually the R&D manager that attends most audits. Smaller sub-milestones are compiled into the programming milestone. The related checklists typically include 10-20 points to go through in the meeting. The evidence of completion is linked to each point in the list, which can be a yield report or a test result, for example.

Company C begins their development process by filling a document called instructions of project activity, which covers the basic information regarding the development process, such as the name and meaning of the project, schedule and data recordings. The project is portrayed in a process form. The process steps on every project include requirements specification (what is to be done and why), preparatory study (schedule and cost estimate) and technical specification (required information to move the product into production) with corresponding milestone audits. These three main milestones are present in every project. Like company B, company C also includes smaller sub-milestones into their product development process, so that there are at least 14 milestone checklists to be reviewed during each project. If the checklists points are not passed in a review meeting, corrective actions are specified, and the meeting is repeated. The project manager is responsible for arranging the milestone reviews and managing the records, changes and repeating the meetings if needed.

There are no major differences between the companies in how the product development processes are documented. Every company has a clear process mapping of the development process with related sub processes included in their quality manual. In company A, the product development process is presented in a flowchart form, with three main development functions side by side and a customer feedback loop from the end point (customer) to the beginning of the process. The three main development functions were linked to included sub-processes and work instructions inside different departments. In company B, the product development process is presented as process maps on the company level as well as on function levels. Milestone checklists support the set processes and list the steps to be done in each part of the development process, ensuring that every task defined within processes is completed before moving forward. Company C's defined process maps include all minimum actions to be carried out during a development project.

All interviewed companies have their own ways to make customer involved in the product development process. In company A, the customer is involved in the beginning and at the end of the project. Customer states the requirements, and the development process itself starts when there is a common understanding of the product. After the product is developed, it is taken to the customer for testing. Depending on the customer

feedback, the product is either produced to agreed specifications or modified according to the needs of the customer. Company B receives product or testing demands from customers. Large customers take part in the development process by setting requirements, validating the product themselves or stating the specifications of which the company must provide test results. The company works often with same customers, so the product testing procedures have been set to comply with customers' tests. This way the testing in product development fulfils the customer test requirements simultaneously. Smaller customers do not participate in development process and product specifications are the only thing they need. Feedback from old customers about old product versions or desirable changes are considered when developing new products.

Company C aims to start every product development project based on a customer need. Some of the projects are paid by the customer, this is when the customer tells the technical specifications, pay for the development and participate in project reviews. If the customer is not paying the development costs, opportunity evaluation is done to evaluate the reality of the customer need. Discussions with customers are held about the product they want, why do they need it from the company and why do they want the product right now. When a product is released, it is preferred to be tested by the customer. Feedback is collected and possible changes are made before the mass production begins.

3.4.4 Key improvements from benchmarking companies

Analysing benchmarking companies' way of working with quality and QMS led to several important lessons:

- A QMS does not have to be a heavy system
- It is highly important that the whole organization participates in QM
- High-level quality targets demonstrate the desired improvement direction
- Defining processes on all organizational areas and following them is crucial for providing high quality products
- Quality should be recognized as one of the main functions and allocated necessary resources

After the benchmarking interviews, the best practices from the interviews were discussed in the case company. The results and best practices of benchmarking companies were compared with main themes found in the current state analysis to see their practical relevance to the found challenges and utilization of a QMS. The findings are summarized in table 12.

Table 12. Summary of best practices identified in the benchmarking study.

Objective	**Best practices from benchmarking companies**
Product development and quality planning	• Defined and documented PD processes in quality manual • Every milestone includes a checklist • Deficiencies are listed as actions and reviewed on next milestone meeting • Process flowcharts for every milestone, include minimum steps required for all development projects • Sub-milestones for different PD functions • Development reviews • Linked evidence for milestone checklist points • Project manager leads the development project • Development reviews are arranged by a developer or the project manager
Quality management	• Requirements and set targets exist for different organizational functions • One or more persons working on quality
QMS	• Covers the whole organization • Defined key processes and sub-processes • Designed responsibilities for processes and metrics • Action list, including improvement plan, targets and KPIs → monthly and annual reviews
Quality targets	• Improving procedures, satisfied customers, continuous improvement of know-how, on-time delivery, hr-targets such as employee well-being, maximum limit for customer claims and product replacements • Reviewed monthly and annually in audits
Quality measures and KPI	• Metrics originate from set targets • Customer feedback, customer complaints • Customer claims • Customer returns • Maintenance work • Delivery reliability, production yield, production capacity • Most common faults • Scheduled PD projects • Development of customer interview-based metrics • Quality metrics are collected by departments and reported to quality manager
Process management	• Key processes are defined and mapped in quality manual • Designated process owners for each process
Internal auditing	• Internal audit after problem has been detected • Annual auditing for every main function – annual wheel of quality • Internal audit plan for schedule and checklists

	• Measurable facts act as the basis for actions
Costs of Quality	• Quality budgeted as a cost centre or "project" • Maintenance costs • Product replacement costs
Testing	• Use of Acceptance Test Procedure (ATP) document • Firmware acceptance tests in relation to ATP document • Testing is planned in the beginning of PD • Test requirements are defined with product specifications • Testing and test yield are reviewed before mass production • Out-of-box auditing
Customer involvement in PD	• Opportunity evaluation – conversation with the customer to evaluate the reality of the customer need • Released products are tested by customers to make changes before mass production

3.5 Current state synthesis

The existing literature describes the maturity levels of QM in an organization as inspection, QC, QA and TQM. Based on this classification, illustrated in figure 21 in chapter 2.1.2, most of the current QM practices at 9Solutions fall into inspection and QC levels. Existing QM elements and their classification against QM maturity levels at 9Solutions are broadly summarized in figure 21. Green colour indicates that the activity is currently performed at 9Solutions, while orange indicates that the activity is either performed to some extent or can be improved. Black text represents QM elements that has not been established at 9Solutions.

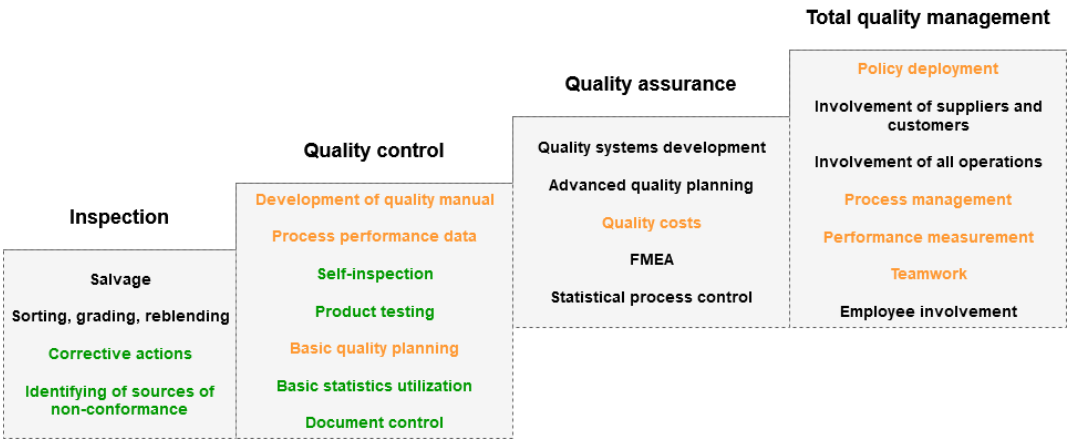

Figure 21. Current QM practices at 9Solutions according to the QM maturity level concept by Dale et al. 2009.

Examining the current QM at 9Solutions indicate that the company has several practices to control and inspect the quality of products delivered to the customers. The improvement direction should be moving the organization into more planned and proactive way of working, to improve product and service quality, reduce the resources used to fix problems afterwards and to consequently increase customer satisfaction. The QMS should be documented and structured according to Annex SL to allow QMS certification in the future. Documentation of existing and planned QM activities should be more systematic and distinctly linked to processes. The challenges in managing product and service quality at 9Solutions can be summarized into key points:

- Lack of active and systematic QM or QMS,
- No systematic quality planning,
- No project organization, productization milestone checkpoints are often ignored,
- Lack of process management and documentation, no systematic quality processes or audits,
- Information silos within departments,
- Measuring organizational performance relies mainly on financial measures,
- Motivation for quality and continuous improvement is present among the employees, but practical means are missing.

As stated in the literature review, quality planning and continuous improvement are the key elements in moving the organization from detective to preventive operation. The benchmarking companies provide guidance to the direction 9Solutions should be taking to implement QMS and how quality should be considered throughout the organization. The interviewed companies emphasized the importance of process management, establishment of both top- and lower-level quality targets, reviewing the measures and the QMS regularly. Since 9Solutions has successfully established internal audit schedule for keeping ISMS standard documents up-to-date, similar annual QMS audit structure would be the easiest to adapt.

In conclusion, based on theory and empirical findings, the improvements should focus on defining a QMS through quality planning, continuous improvement and establishing performance measurements and a process management framework. As a result, a process based QMS is created, that covers the case organization process by process and that is being audited and improved at regular intervals. Figure 21 summarizes the best practice concepts from theory and empirical study. Progress towards set goals should be monitored with organizational KPIs and later with process measurements, as the measurements and process management are developed in the company.

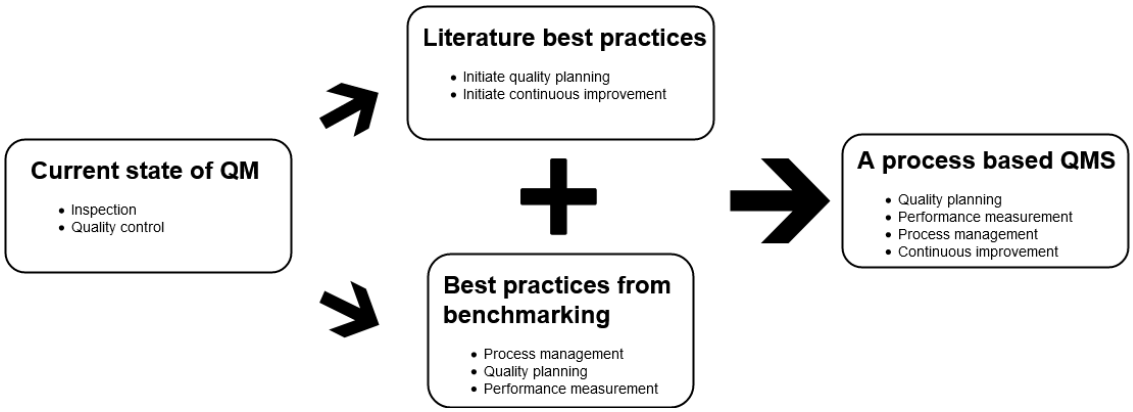

Figure 21. The proposed direction for improvement areas based on literature and empirical findings

4 RECOMMENDATIONS FOR FUTURE IMPROVEMENTS

This chapter provides an improvement framework on how to improve current QM practices at 9Solutions for increased product quality. The proposed improvement areas are the result of theoretical input and empirical research presented in chapters 2 and 3. Additionally, plans for the implementation timeline and system documentation are presented.

The primary goal of the recommendations is to initiate a change from a detective to a more preventive way of working within the case organization, by implementing several QM elements in a top-down manner. The proposed QMS framework consists of QA and TQM elements, that promote a more preventive way of working and help to unify quality culture within the organization. The direction of change in QM with the improvements is illustrated in figure 22, that is based on the QM evolution concept by Dale et al. (2009), described in the literature review chapter. The system with the proposed quality assuring elements will in turn further encourage improvements in existing inspection and quality control elements, as processes and metrics will be more defined and manageable, and feedback from the system is regularly brought back into the quality planning phase.

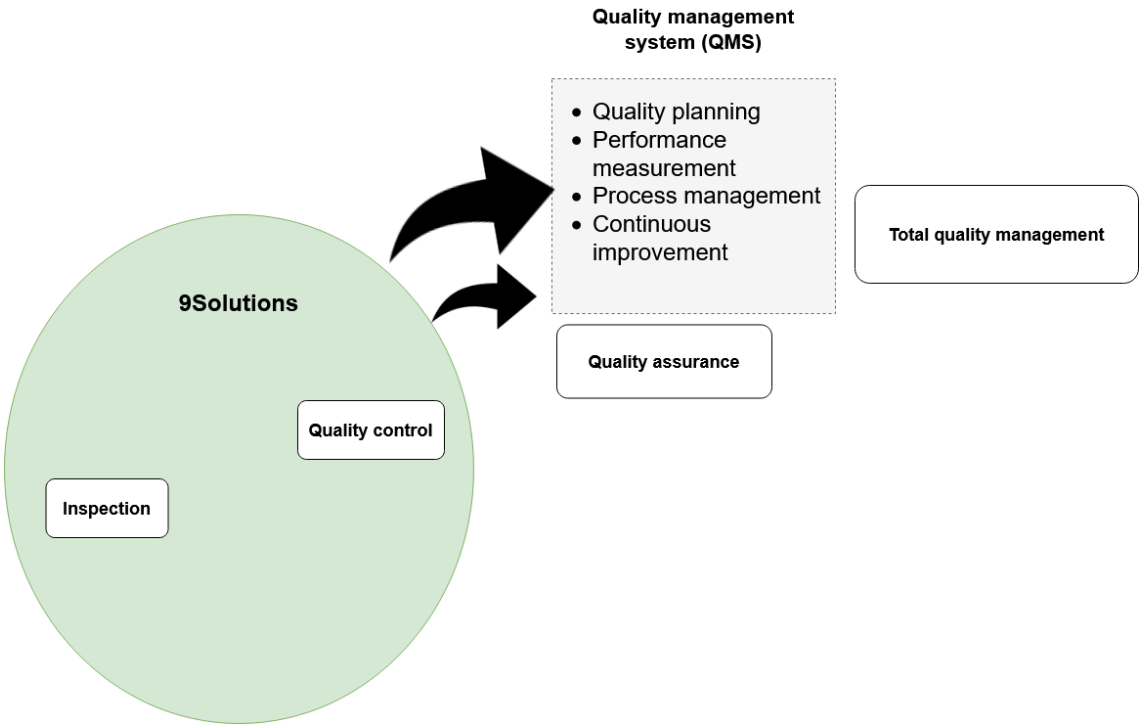

Figure 22. The direction of desired change in QM at 9Solutions, based on QM maturity levels concept.

Quality planning improvements will help 9Solutions to begin the quality journey towards better product quality and manageability by updating their quality policy and define corresponding quality objectives and measures. Quality planning has also role in project environment, where project quality plans and objective idea evaluation ensure that right projects are chosen, and that they fulfil the set quality requirements.

Improvements for process management and measuring performance provide greater clarity in the current process flow of at 9Solutions and help to measure the right things and track progress towards set quality and organizational objectives. Review methods and audits are utilized to keep the system always up to date, adapt to changes and continuously improve the performance of the processes and the system. Together, these improvements drive continuous improvement like the beforementioned PDCA cycle. Achieving long-term quality improvement requires that the culture in the organization is conductive to quality, and therefore management must show their commitment by organizing quality improvement teams and projects.

4.1 Quality planning – a QMS implementation prerequisite

Top management should update the existing quality policy to match the revised vision and mission statements or establish a new organizational quality policy to demonstrate its commitment to quality and continual improvement of QMS by setting short- and long-term improvement goals. The policy should be followed by establishing quality objectives on both departmental and individual level. Establishing quality policy and concrete objectives play an important role in securing the QMS implementation and bringing quality to daily work at 9Solutions.

Current quality objectives at 9Solutions are linked to customer satisfaction, timeliness of product delivery and SaaS availability. These objectives are customer oriented, but do not necessarily drive continuous improvement, as they are already being achieved. Therefore, updated short- and long-term quality improvement objectives should be established for different functions, and existing objectives should be revised. Each objective should be accompanied with a plan on how to reach the objective. The quality objectives should have direct link to quality policy, that is further linked to the philosophy, vision and mission of the company.

Defining quality objectives should begin with simple targets, that can be tightened up and modified over time. The high-level quality objectives should derive from the quality policy. For example, high-level quality objectives for 9Solutions can be (according to current 9Solutions quality policy):

1. "We develop reliable products to ensure safety and communication in healthcare"
2. "We solve critical errors in our software platform as soon as possible"
3. "Our employees are prepared for their tasks"

The high-level quality objectives are then divided into one or more quality KPIs and measures. These concrete quality measures should be defined according to SMART and be more specific than the quality policy or quality objectives. Examples of specific measurable quality KPIs and corresponding measures for 9Solutions can be such as:

1. KPI: Develop and produce high quality products
    - Metrics: Product returns, product services, production yield, most common defects, lead time of PD projects, projects completed on time, on-time delivery rate, customer satisfaction, % of suppliers evaluated
2. KPI: Maintain high availability of the IPCS platform
    - Metrics: System reliability, average time to solve a problem, maintain iso 27001 certification, number of bugs in the cloud platform
3. KPI: Professional and happy employees
    - Metrics: Employee training rate, employee satisfaction, process time to maturity

To make the quality policy and objectives integrated into workspace and communicated to employees, a link between the policy, objectives and KPIs must be demonstrated distinctively. A KPI tree, presented in figure 23, can be a helpful visualization tool to understand the links between quality objectives and measures. The quality objectives, KPIs and measures must be communicated throughout the organization, to ensure that everyone is focused on the same goals on different levels and parts of the case organization. Top management shall also review the quality policy, quality objectives and KPIs regularly to ensure that the measurements are current and aligned with the company's strategy.

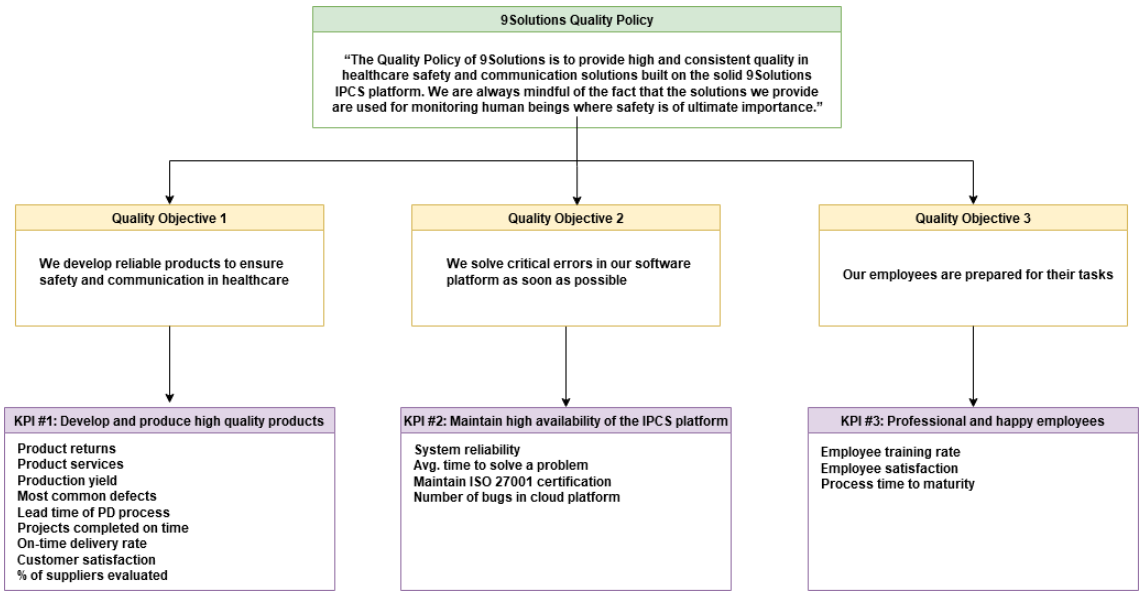

Figure 23. A KPI tree example for quality objectives and measures.

4.1.1 Project quality planning

After identifying processes and related quality control activities, including documentation and required resources, standardized quality planning can be initiated for different types of projects, such as PD projects. A standardized process and a product plan template are requirements for applying project quality planning. A product development plan template should include information about the purpose and scope of the project, resource allocation and the process to be followed, including milestone checkpoints. Based on the template, a quality plan can be created for each project. The project quality plan should include information, such as:

- Purpose of the project quality plan
- Link to relevant QMS documentation
- Quality requirements for the product
- Product release criteria
- List of planned test activities
- Project measurements
- Process deviations from the standard project model (accepted by the management)

4.1.2 Defining customer requirements

Currently, objective product idea evaluation is lacking in the case company's productization process. A more controlled method of analysing customer needs and transforming them into technical specifications helps in sorting out unviable products and understanding the relationships between customer requirements and corresponding product and service design requirements. Currently, complex processes can be difficult to integrate due to lack of resources and process management. As key PD processes develop along with the QMS, cross-functional design methods, such as QFD can be brought into the planning and developing of new products and services.

4.2 Measuring organizational performance - Enabling continuous improvement

Measuring organizational performance is a fundamental part of TQM philosophy and the empirical research show that establishing organizational, functional and individual performance targets and measuring the performance of different functions is a common way of monitoring performance of an organization, which also applies at 9Solutions. Developing performance objectives and measuring progress towards them is important to make measurements an effective tool for organization-wide process improvement at 9Solutions. The current measurements at 9Solutions focus mainly on customer satisfaction and business results and should be revised to match the company's updated vision, mission, and strategy.

9Solutions can benefit from a structured and interlinked organizational performance measurement system as a part of the proposed QMS. Oakland (2014) presents guidelines in how to define measurements for organizational performance, that can be utilized to some degree in the case company. The process starts with defining several critical success factors (CFSs), that can be viewed as the "building blocks" for the company's mission statement. The CSFs should answer the question "what we must have?" in order to achieve the mission statement. Each CFS is accompanied with measures (KPIs), targets and owners. The framework aims to bring the top-level targets throughout the organization, so that measurements on the lower levels are aligned with

the top-level goals. Establishing the top-level measurement framework also supports identification of the key business processes (in chapter 4.3), that are important part in process management and defining the QMS for 9Solutions.

At the time of writing this chapter, the case company is finishing its vision, strategy, and mission statement renovation. Therefore, the PMF model explained earlier in this thesis can be used to create an up to date top-level measurement framework at 9Solutions to support QM functions and the QMS. This way the QMS will cover the most important business processes and measures and help defining the scope of the QMS.

4.2.1 Creating a top-level measurement framework

Defining organizational performance measurements starts with looking into company's mission statement. Based on the mission statement, critical success factors are identified, stating the factors that are necessary for the organization to achieve its mission statement. The number of CFSs should be three to eight, according to the authors in existing literature. The CFS should cover all stakeholder groups, shareholders, society, customers, and employees. Measurable KPIs and targets are defined for each CSF to set a performance baseline and to see the relationship between CSFs and KPIs – to make sure the things that right things are being measured and are aligned with the company's top-level goals.

Defining KPIs and targets must follow certain rules. As a rule of thumb, measurement design should follow the SMART objectives; the measures should be specific, measurable, attainable, relevant and time bound. Setting the KPIs for the CSFs and evaluating their interactions with processes could be done in simple matrix presented in table 13. The CSF owner has the responsibility to define the KPIs and targets. The KPIs should be balanced according to four categories: short term vs. long term, external vs. internal, leading indicators vs. lagging indicators and objective measures vs. subjective measures. Examples of CSFs for 9Solutions are presented in table 13. CSFs should be reviewed and updated every time the company's top-level policies and statements are changed or modified.

Table 13. CSF examples for 9Solutions.

CFS No.	CSF (We must have…)	CSF owner(s)	KPIs/targets	Core processes impacting this CSF
1.	Sales growth	CFO	Annual sales growth rate / > 10 %	Market research, productization
2.	Loyal customers	CEO	Customer satisfaction score (NPS) / > 70.0 Customer retention rate (CRR) / > 90 %	Productization, customer support processes, order to delivery process
3.	On time product development and delivery	R & D Manager, Operations manager	Proportion of PD projects completed on schedule / > 75 % Avg. cycle time for NPD process / < 6 months	Productization
4.	An effective product strategy	CEO, After Sales Director	Degree of strategy communication / 95 %	Strategy planning and deployment
5.	Up-front homework	CEO, CFO	Financial measures, such as Expected Commercial Value (ECV), Net Present Value (NPV), Productivity Index (PI)	Financial evaluation
6.	High product functionality	R & D manager, After Sales Director	Product performance / >95 % test pass	Productization, Product development

A balanced scorecard, described in QM chapter, can be utilized at 9Solutions to balance performance measures in financial, customer, internal business, and learning and growth perspectives. The CFS and KPIs can be distributed into the balanced scorecard framework, as presented in table 14. The CFSs act as the "objectives" in the BSC context and KPIs correspond to "measures." Quality objectives derived in the chapter 4.1 can be added to the BSC context. Linking quality objectives and KPIs to the BSC environment helps broadening the BSC perspectives. Each category in the scorecard should include between four to seven measurements. If the resulting number of objectives and measurements is too low in any category, more can be developed according to the BSC guidelines. At 9Solutions, the performance measurements should focus especially measuring the productization and PD processes, as they represent fundamental core processes of the company, with a direct influence on the quality of resulting product or service.

Table 14. A BSC framework example for organizational performance measurement at 9Solutions.

Perspective	Objectives (/CFSs)	Measurements (KPIs)	Targets	Initiatives (action plans)
1. Customer	CSF no. 2 - Loyal customers	Customer satisfaction score (NPS)	> 70.0	
		Custromer retention rate (CRR)	> 90 %	
	CSF no. 3 - On time product development and delivery	Proportion of PD projects completed on schedule	> 75 %	
		Avg. cycle time for NPD process	< 6 months	
2. Internal business	CSF no. 4 – An effective product strategy	Degree of strategy communication	> 95 %	
	Manufacturing excellence	Avg. product assembly cycle time, unit cost and yield		
	CSF no. 6 - High product functionality	Product performance	> 95 % test pass	
	Decrease the amount of post sales services	Product warranty, repair and return rate		
3. Innovation and learning	Reduce product and service development time	Avg. time from design to production	< 6 months	
	Technology leadership	Time to develop next generation product(s)	< 2 years	
	CSF no. 5 – Up-front homework	Financial measures (ECV, NPV, PI)		
	Meet mission goals	Self-assessment for continuous improvement	Annual	
	Quality objective no. 3 – Prepared employees	Employee training rate, employee satisfaction, process time to maturity		
4. Financial	CSF no. 1 Sales growth	Annual sales growth rate	> 10 %	
	Increase return on investment (ROI)	ROI	> 10 %	

The results from BSC should be reviewed regularly and linked back to the strategic planning phase of defining and updating KPIs, as illustrated in figure 24. Reviewing the scorecard results regularly and acting on observations allow long-term strategic planning and control of the key process performance. As with current KPIs at 9Solutions, the derived metrics are reviewed, and action plans are renewed monthly or biweekly in management meetings or QMS audits.

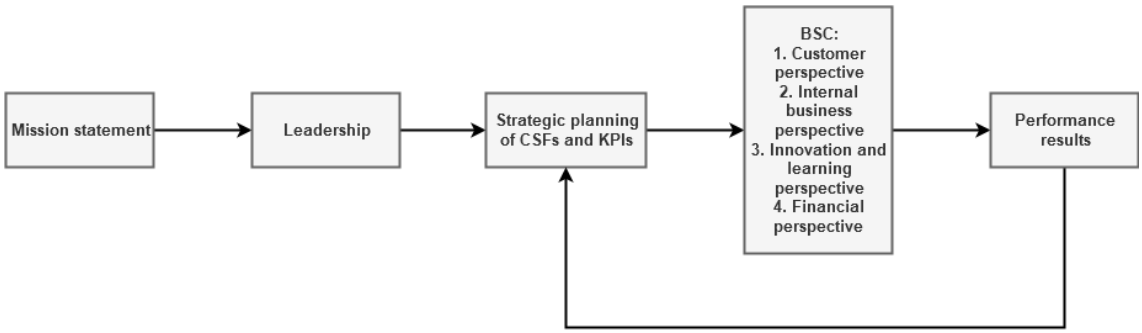

Figure 24. Reviewing and planning of BSC framework.

Measuring CoQ is relevant in performance measurement context. Measuring quality costs according to the models presented in the existing literature may not be applicable yet at the case company, but it should be given attention after the QMS has been developed further. For a process based QMS, the process cost based CoQ evaluation would be the best option, as the quality costs are linked to relevant processes. The benchmarking companies also provide guidance on what aspects to include in the quality cost measurement.

4.3 Defining key processes and process management

Process approach is one of the key elements of the proposed QMS framework at 9Solutions. The ISO 9000 standard series also highlights the importance of process approach, considering the most important organizational processes and the QMS itself as a process. Defining processes should start in a top-down manner, first focusing at the core business processes as a whole and eventually looking inside each process. Defining core cross-functional processes will help 9Solutions to recognize the most important

value adding core activities and are later important part of defining targets for organizational performance according to CFSs. Key processes answer the question "how the mission statement is achieved?", as described by Oakland (2014). This chapter focuses on defining and mapping processes according to the set top-level targets and connecting process management into performance measurement framework as a part of the QMS.

Understanding the core processes and their priority can be accomplished by comparing the identified core processes with the amount of impacts they have with the CSFs, by assessing their current performance against the set targets, or by creating selection criteria for processes, as discussed by Juran (1998). The proposed performance measurement framework described in chapter 4.2 includes defining the CSFs at 9Solutions and should be utilized also in key process identification. The more interactions the identified processes have with CSFs, the more priority they should get in the creation of process management infrastructure.

4.3.1 Process mapping and standardization

Defining organizational processes should start with identification of all the major functional areas/departments of the organization and mapping the cross-functional key processes within these "metaprocesses." At 9Solutions, the main organizational metaprocesses are already identified and presented in figure 25, based on the organizational chart categories.

Figure 25. Metaprocesses at 9Solutions.

Next, the core business processes within the metaprocesses are derived by analysing CSFs and process relations. All the high-level core processes necessary for set CSFs must be identified. Each core process must be sponsored by a management team member, who makes sure that enough resources are available for process mapping and improvement. Every core process should be accompanied with basic information of the process, such as process owner, the purpose and scope of the process (what the process includes), process inputs and input providers/suppliers, and outputs and output receiver(s)/customer(s). Details of individual processes are not necessary at this point.

After the core processes within metaprocesses and their priorities have been defined, lower-level organizational processes within these core processes can be mapped. The mapping of these sub-processes should be done in the form of process flowcharts, instead of a process map view of the high-level processes. As with defining key processes, workshops should be arranged with management and practitioner personnel from the departments that carry out the process. Also, representatives from departments that provide inputs to process as well as those who receive outputs from the process should be included in the meeting. For example, the resulting process flow and hierarchy may follow IDEF3 process capturing methodology. A process flow of an outdated "9Solutions Order Fulfilment Process" is presented as an example of such a diagram in figure 26. IDEF3 also includes Object State Transition Description model, that can be used for product centred operational and deployment processes, such as assembling or installing products.

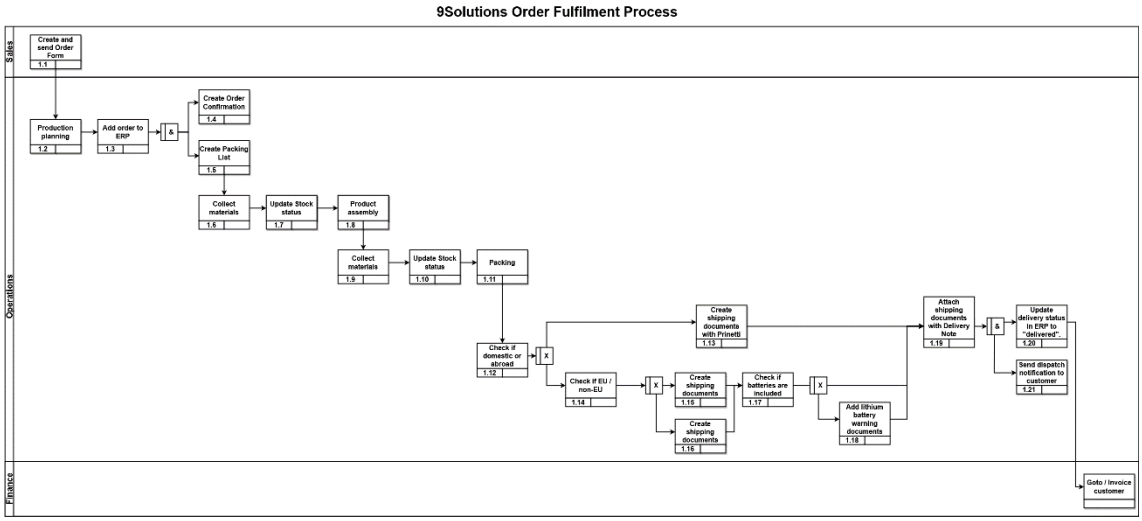

Figure 26. Example of process mapping using IDEF3 process capturing method

Process maps and flowcharts alone do not provide enough guidance to practitioners of the processes. Therefore, additional process documentation is necessary for consistent process execution. The additional process documentation should be in a standardized format such as the SIPOC card, presented in figure 27. Processes, sub-processes and included process activities are described as procedures and work instructions in the quality manual.

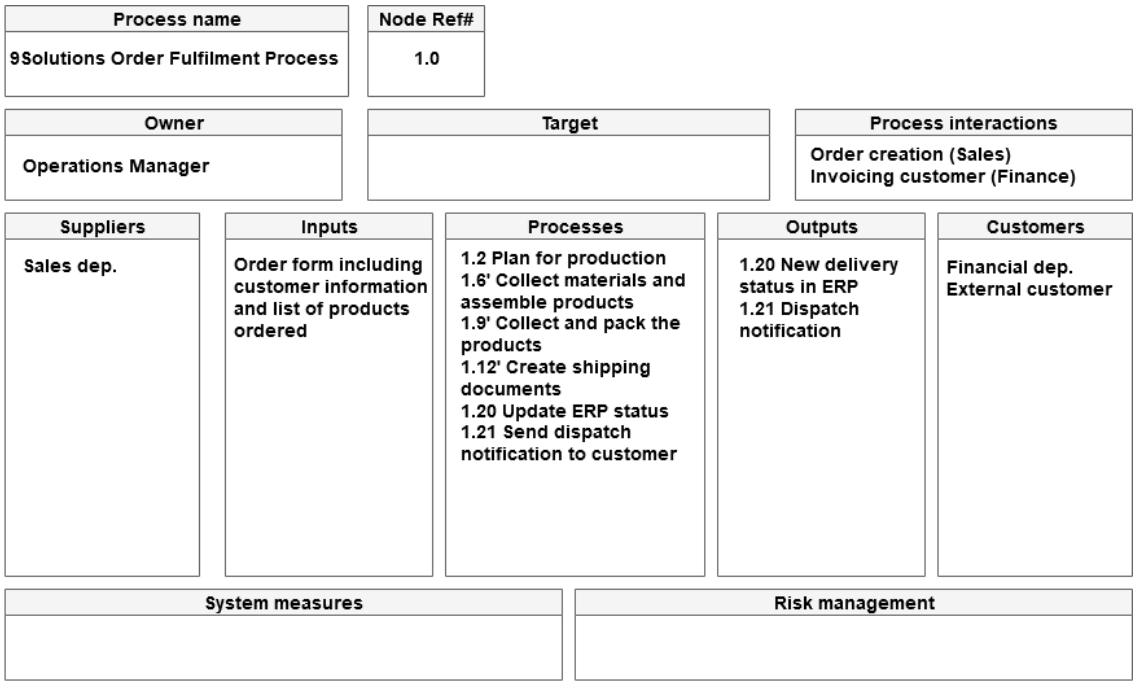

Figure 27. Example of the SIPOC card documentation of the 9Solutions Order Fulfilment Process.

Collecting the process documentation data should be the process owner's responsibility and creating the process documentation should then be distributed among qualified personnel from the departments that are involved in the process. The personnel creating process related documentation should be coordinated by the process owner and relevant management personnel from the departments that are involved in the process. The participation of employees allows common understanding and involvement in process documentation and QMS ownership activities. The more detailed the process maps and the process documentation are, the easier it will be to expand the performance measurement framework to different level processes.

Currently in the case company, the productization and product development processes are not documented to any greater extent. Thus, a defined top-level process flow

diagram of the productization process should be created with corresponding checklists, process owners and responsibilities. Additionally, PD functions' sub-processes should be defined to create sub-milestone checklists, which can be summarized in the main milestone reviews. A dedicated person, such as project manager should be responsible of keeping track of the data collection for the gate meetings and make sure that every point in the milestone checklist is fulfilled before moving forward with the project. When processes are well defined and detailed, business process engineering and individual performance measurements can be applied to further improve the process management framework as a core part of the QMS.

4.4 Implementing and improving the QMS

The QMS implementation and maintenance should be given attention and adequate resources from the case company's top-management. A cross-functional QMS team should be formed to carry out the QMS implementation phase. The team should consist of top managers of different organizational functions. At 9Solutions, the proposed QMS planning and deployment team composition would include the CEO, CFS, operations manager, R&D manager and after sales manager. The managerial quality meetings should first focus on the QMS implementation process by allocating resources, establishing performance measures and creating core process documentation. After the QMS foundations have been created, a regular audit schedule should be established to ensure that the system is continuously improving and can adapt to changes.

The required implementation time will depend on the available time and resources. During the QMS implementation, regular managerial meetings shall be held in a frequent manner. For example, a 6-month period could be enough to define the core elements of the QMS at 9Solutions. The implementation process can be divided into three main phases: top-level quality planning, establishing performance measurement framework and identifying and documenting core processes. Realistically, each phase should take no more than two months. The suggested implementation process timeline and process-steps are visualized in figure 28.

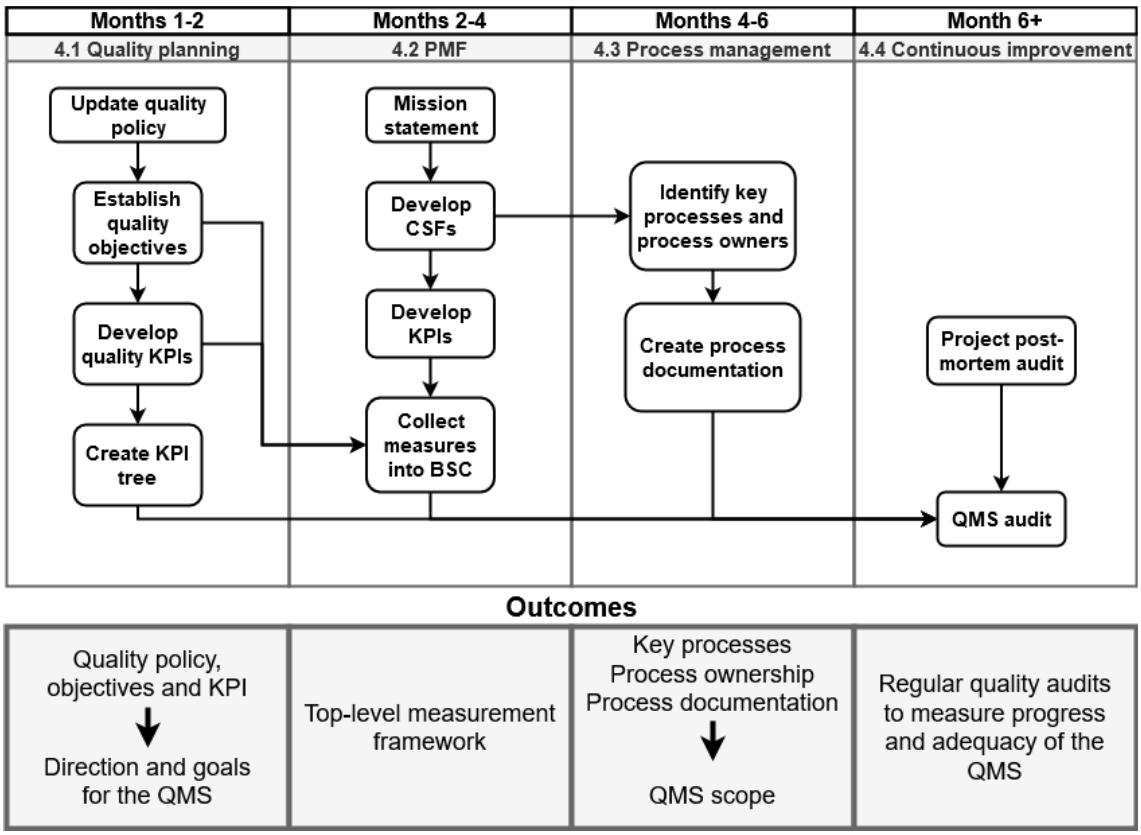

Figure 28. The proposed QMS implementation process and its outcomes.

4.4.1 Internal audit

The proposed process based QMS should be regularly audited to determine its effectiveness and adequacy. After the QMS has been implemented, monthly quality meetings should be prepared by the management quality representative or the quality manager. The meetings should follow a specified agenda and include routine tasks and specific subjects that are stated in the annual quality plan. A management quality representative or quality manager should be allocated the responsibility to plan, prepare and perform audits as well as report the audit results to top-management.

On top of the regular managerial quality meetings, an annual quality audit plan should be prepared and performed. Quality audits should first focus on managing the QMS implementation and later on ensuring that process documentation is constantly updated according to the company's current strategy and market needs. The QMS audit program should cover projects, products and processes. For all types of internal audits, the chosen auditor should be independent of the area audited. The auditing process, presented in figure 29, should apply to all audit types. The process starts with planning

and preparation of the audit by the quality representative and auditor. After the audit has been performed, the results are analysed and shared with auditees. Finally, the audit results are presented in managerial quality meetings, and follow-up actions are determined if seen necessary.

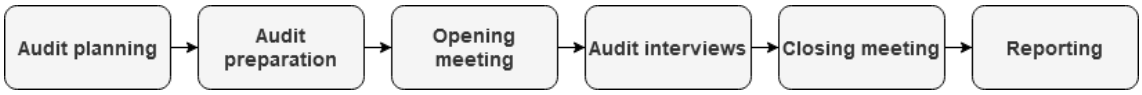

Figure 29. The proposed audit process.

Product audit

Product audits should be prioritized for new products, to assess how well the product or service qualifies to the intended use of the product or service. Therefore, involving customers and end-users of products and services to the audit process should be considered.

Process audit

Auditing processes should be a permanent part of the proposed QMS framework. After the QMS has been established, process audits should assess how well the assessed process is executed according to the documented information of that process. As a result, the need for changing the process documentation or the process itself can be noted. Existing process evaluation models, such as Process and Enterprise Maturity Model (PEMM) or Capability Maturity Model Integration (CMMI), should be considered to make the evaluation method systematic and to provide information on how specific processes can be further developed as a part of the QMS.

Project post-mortem audit

Applying continuous improvement and learning into the 9SPLC productization process can be established with project post-mortem audits for development projects. The post-mortem audit acts as the last development phase after the launch to market. The post-mortem analysis should happen after every project, identifying the strengths and weaknesses of the development and productization process execution. The results will

be used in the planning of next similar project. Reviewing project execution can reveal recurring models in the projects that many cause faults and delays or challenges in process improvement. The post-mortem analysis also supports the personal knowledge of participants. Furthermore, improved PD documentation practices and ongoing review of the company's productization process can lead to improvement opportunities.

Currently, "lessons learned" type activities are only organized in software department instead of utilizing them cross-functionally after a larger-scale project. The project postmortem audit is a principle to initiate corrective and preventive actions to address opportunity for improvement as well as to initiate actions to ensure that the positive experiences are repeated in future projects. A suggestion for project postmortem audit process and related documentation is presented in figure 29.

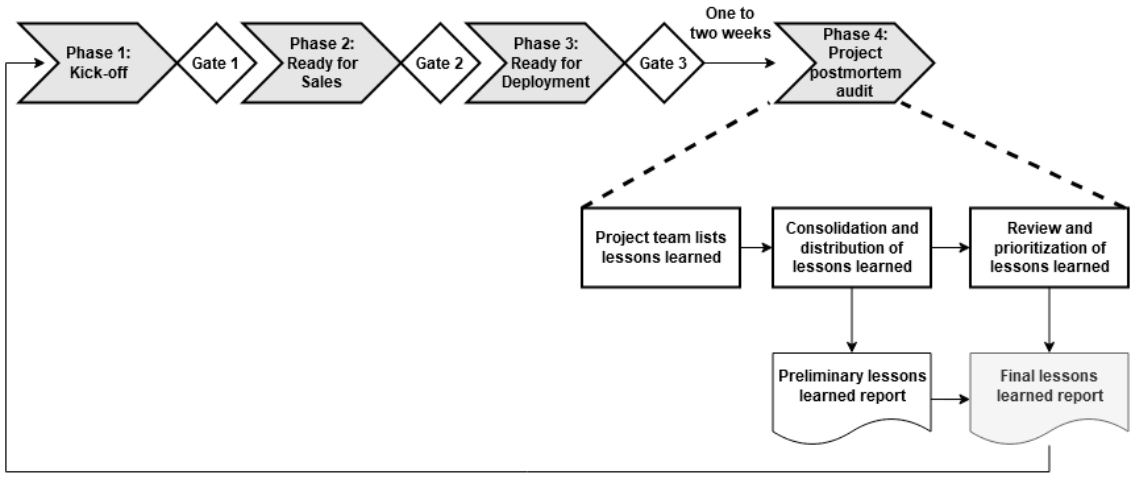

Figure 29. The project postmortem review process as a part of the productization process

Self-assessment

Self-assessment tools can help 9Solutions to monitor and improve its performance. Self-assessment tools, such as EFQM or MBNQA should be considered after the QMS has been implemented and the cultural foundations for QM are achieved in the organization. Self-assessment

4.5 QMS documentation

Documenting the QMS should begin from higher level documents that are linked to lower level documentation, such as core processes and their sub-processes. The QMS documentation may be stored in the company's cloud-storage, with direct links to necessary external documents. The intended QMS process documentation covers the identified core business processes. As recommended in existing literature by Nanda (2005) and Dale et al. (2009), the QMS documentation should be divided into four hierarchical levels. At 9Solutions, the QMS should include the following documents:

- The first level of documentation should consist of:
    - Quality manual
    - Organization chart and the QMS management team
    - Process map of core business processes
    - Quality policy, objectives and KPI
    - The CSFs and organizational performance KPIs
- Level 2:
    - Procedure documents describing the core processes
    - Performance measures of core processes
- Level 3:
    - Procedure documents describing sub-processes
    - Work instruction documents
    - Individual performance appraisal methods
    - Templates (productization milestone checklists, quality audits)
- Level 4:
    - Audit reports
    - Project information (documents, records, data)
    - All other reference documents

Quality manual

A QMS requires the development of quality manual, that describes how the QMS works. At 9Solutions, ISO 9001:2015 based quality manual exists partly. Following

ISO 9001 requirements is a good way to define QA elements into the QMS and allow for certification later if it is seen necessary. The Annex SL form of the ISO standard allows combining the current ISMS system and the QMS into a business management system, covering the organization's quality and information management aspects in a standardized format, promoting the lean management philosophy. Compared to ISO 9001:2015 certification standard, the proposed improvements will help to define and document the following clauses:

- The top-level quality policies and objectives – clauses 5.1, 5.2 and 6.2.
- The performance measurement framework – clauses 9.1, 9.3
- Process approach – clause 4.4
- Defined product and service design and development process – clause 8.3
- Internal auditing – clause 9.2
- Customer involvement – Clause 8.2
- Continuous improvement of the QMS – clause 10.3

Process documentation should be presented in the quality manual in the following way:

1) The core business processes should be presented in a simple process map (first level of detail), with each process inputs and outputs described in a SIPOC card.
2) Each core process is described in a high-level procedure document, that describes how the process is carried out; what activities are involved in the process, when the activities are performed and who performs what actions.
3) Work instructions form the low-level documentation of a process, describing in detail how to perform activities and tasks within a process step. Work instructions define activities in a step-by-step manner to accomplish the activities in a process. Work instructions are necessary only for activities that need a detailed step-by-step guidance for performing the activity.

5 CONCLUSIONS

The objective of the study is to provide a quality improvement framework for the case company in the form of a QMS. The improvement recommendations are based on existing literature findings and empirical analysis of the case company and benchmarking companies. The key concepts of quality management, quality management systems, productization and product development create theoretical background for the study to assess the current state of the case company and to clarify improvement direction. The identified best practices from the benchmarking study were also utilized in the construction of the improvement framework. As a result, a process-based QMS is presented, aiming to systematize quality management at the case company and adopt a more preventive approach to quality issues.

5.1 Key results

During the last decades, QM has developed from routine inspection activities to supply-chain wide process of continuous improvement and is now considered an important managerial tool in both small and large enterprises. Managing quality aims to detect and prevent problems by planning, monitoring and continuously improving organizational processes. Systematic quality management helps organizations to increase customer satisfaction by involving people on all levels, setting concrete and measurable targets, providing clarity in processes and measuring the organization's progress towards set goals. SMEs may find a QMS implementation necessary when the company is rapidly growing, moving their business abroad or want to improve their product or service quality. Also, external customers may require that the company has a certified QMS in place. However, if the sole reason for QMS implementation is to get certified or pass a customer audit, a lot of QM benefits may not be achieved. The real motivation for QM should derive from management initiative to enhance customer satisfaction and improve company's performance.

Current state of QM in the case company revolves around inspection and quality control, with some quality assuring activities. Managing quality is not systematic in a

sense that there is no documented QMS or a designated person for managing quality. The lack of systematically defined processes and process owners has led to information gaps between organizational functions. Quality planning is not practiced systematically in the company's productization process, which forces a detective approach to finding and fixing problems. Also, the lack of dedicated project teams and project managers lead to unmanaged productization process where milestone reviews are ignored, and therefore crucial quality control of the development process is missing. The lack of quality manager or management quality representative means there is no proper initiative to establish systematic QM. The benchmarking survey demonstrated the importance of a QMS that covers the most important areas of company's operation. A clear view on organizational targets, core processes and process owners, planning activities and auditing promote continuous improvement and can be considered as the best-practices of managing quality among the benchmarking companies. These aspects can be viewed as the desired improvement direction also at the case company.

This study suggests that implementing quality assurance tools and establishing a QMS will help in applying a more preventive approach into quality to improve product quality at the case company. Recommendations provide an improvement framework for the case company. Establishing QMS at the case company should begin with a top-down approach of redefining quality policy, objectives and KPIs. Communicating the quality goals throughout the organization help forming a mutual understanding of quality and promoting quality culture among the employees at the case company. The established quality policy and goals act as the improvement direction for the whole QMS. The QMS should then be structured around the core organizational processes. The most crucial business processes are objectively identified through the establishment of an organizational performance framework. The company's mission should be used as the base for creating CSF with KPIs that act as performance metrics for the top-level processes. Performance metrics provide information about company's progress through balanced set of performance metrics and targets. The process management approach allows better management of core business and continuous improvement of the system and helps to cover all areas of the company's operation that are seen necessary to achieve the main organizational targets. The QMS implementation requires full management support and establishing a QMS team consisting of the members of top

management is advised. The allocated managers should be responsible for providing adequate resources to the QMS implementation and development, as well as promoting quality culture among their areas of responsibility.

5.2 Theoretical contribution

QM has been studied extensively and the key concepts around the topic are well established. Several principles and frameworks have been developed for managing quality in social and technical aspects that affect quality within an organization. Quality is usually understood as satisfying customer and meeting required specifications. Earlier studies conducted by Oakland (2014) and Dale et al. (2009) promote a systematic and preventive approach to quality, while also addressing the importance of quality control. The modern, preventive approach to quality highlights the importance of establishing quality objectives, involving people and performing quality planning, so that continuous improvement is achieved. The distinction between detective and preventive QM principles allowed to assess the current state of QM in the case companies, as the empirical findings from studying the case company and benchmarking companies support the QM maturity level classification described by Dale et al. (2009).

The relationship between QM and productization has not been discussed to any greater degree. Productization aims to produce products and services of high quality, but the practical models for developing QM into whole productization process have not been established. Thus, this study complements existing literature on productization and quality management by linking the concepts. On the other hand, quality has been widely studied in PD environment that has a direct impact on the quality of the resulting product or service (Ulrich & Eppinger 2012, Oakland 2014). The quality concept has been brought into PD with methods such as project-specific quality planning and QFD (Zairi & Youssef 2009).

5.3 Managerial implications

This study demonstrates the importance of QM in both small and large enterprises. QM should start from management initiative and be applied to all functions of the organization, that are seen crucial to satisfy customer and meet internal and external requirements. Systematizing QM by establishing a QMS can allow a more systematic way in understanding the needs of the customer, manage risks, remove waste, improve cross-functional communication and improve the organization's business performance. Implementing a QMS is seen as a method to raise company's maturity level as the company grows or expands to new market areas. In SMEs that wish to implement a QMS, the main principles and scope of QM should be defined first. As QM in general, also establishing a QMS should be a planned, company-specific process, guided by existing QM concepts and management know-how.

The study indicates, that in the context of SMEs with no QMS, the implementation should start with creating quality objectives and identifying and managing the core functional elements of the organization towards set goals. If seen necessary, the system can be expanded further to cover more organizational functions after the main functionalities have been established. Measuring organizational performance guides the managerial decision making and future planning, thus promoting continuous improvement within an organization. Especially product development-heavy companies should establish quality planning procedures for projects, ensuring that the voice of the customer is considered in their development processes from start to finish. Proper quality planning should be regarded as one of the key points in ensuring the quality of resulting product or service, as well as in successful QMS implementation.

5.4 Validity and reliability

The validity and reliability of the research results can be assessed according to Yin's (2009) four main criteria for evaluating the quality of research design. The evaluation criteria consist of *construct validity*, *internal validity*, *external validity* and *reliability*.

Construct validity requires the use of multiple sources of evidence and establishing correct operational measures. The literature review chapter collects information from several academic sources, so that quality management is considered from different viewpoints. Therefore, construct validity can be seen successfully achieved for the study's theoretical part. The empirical part studied the current QM status at the case company through several semi-structured interviews and comparing the results against key concepts of the literature review. Benchmarking interviews were also semi-structured in nature to allow open discussion about the topics. The benchmarking interviews brought a new perspective to the study and the findings were found useful in the construction of the improvement framework. Semi-structured interviews can be affected by inaccuracy and by the interviewer's influence on the interviewees (Bryman & Bell 2003). Obtaining information from several different sources aim to minimize these weaknesses. The large number of internal and external interviews, as well as internal data collection have provided good construct validity for the empirical part of the study.

Internal validity of the study can be evaluated through causal relationships, and therefore is not fully relevant in case studies (Yin 2009). In this study, several literature sources form the basis for the thesis worker's reasoning in empirical part of the study and in construction of the improvements. Hidden factors can have effect on concluding causalities, and therefore the research focuses on improving the current state by constructing an improvement framework, rather than examining causalities between x and y.

External validity considers how well the research results can be generalized outside the immediate case study (Yin 2009). The literature review presents a generic but versatile look into different quality management approaches, so that the key findings can be regarded as theoretical QM guidelines for improvement. The improvement framework is specific to the case company and can not be directly transferred to any external context. However, the generic key concepts behind the framework could be applied in any organization that wishes to systematize their QM by implementing a QMS, especially in similar sized SMEs.

The last criteria, *reliability*, evaluates the repeatability of the study. Meaning if the research study process is repeated by a later investigator, would he end up with same findings and conclusions. (Yin 2009) The study supports the reliability aspect by describing the research process and topics, and their utilization in empirical findings and improvement suggestions. The research questionnaires are also included as appendices. The key concepts around QM has been well established and haven't changed a lot recently. Therefore, it can be concluded that another researcher would end up with similar conclusions for improvement proposals. However, another researcher might end up with different results, as the outcomes of semi-structured interviews can vary depending on the interaction between the interviewer and interviewees. The business environment and company's internal procedures are also constantly developing, and thus the empirical research could yield some different results if it was to be performed on a later point of time.

5.5 Future research

Even though QM has been studied extensively, some areas of interest for further research were discovered during the study process. This chapter presents the identified gaps in existing literature, some of which could also benefit the case company.

While the existing literature on QM is rather extensive, more research could be done on QM in SME context. Current QM models are mostly applicable to large organizations with abundant resources and personnel to manage quality effectively. Implementing a QMS requires increased amount of system documentation and continuous ongoing support, which can be repulsive factors against QMS implementation for companies that work with little resources. However, as the benchmarking study demonstrates, successful QM can be also achieved in SMEs. Therefore, SME-specific guidelines and practices for managing quality in small enterprises and growing organizations should be examined and developed further. Lean philosophy has been widely adopted in SME business environment, and more research should consider QM's significance in lean organizations. Further research is also needed to assess the relationship between the QM principles and productization and how QM can support effective productization practices. QMS implementation methods and schedules vary between organizations and

are not discussed to any greater degree in existing literature. Therefore, more research is needed to define effective models for QMS implementation process in both small and larger organizations.

In the case company, managing quality and establishing a QMS should begin with implementing basic concepts described in this study. Further research could observe the QMS implementation process and its short- and long-term effects within the case organization. Development of quality culture within the case organization can allow the use of self-assessment models, that can be useful for the company to observe its progress towards operational excellence. External QM factors should also be evaluated, such as supplier relationships and involving external customers into company's processes. Regular external benchmarking methods can be a helpful tool for the case organization to develop their managerial systems, including the QMS.

6 REFERENCES

Anttila, J. & Jussila, K. (2017). ISO 9001:2015 – a questionable reform. What should the implementing organisations understand and do? *Total Quality Management & Business Excellence.* 1-16. 10.1080/14783363.2017.1309119.

Assarlind, M. & Gremyr, I. (2014). Critical factors for quality management initiatives in small- and medium-sized enterprises. *Total Quality Management & Business Excellence,* 25:3-4, 397-411.

Baines, T., Lightfoot, H., Benedettini, O. & Kay, J.M. (2009). The servitization of manufacturing: A review of literature and reflection on future challenges. *Journal of Manufacturing Technology Management.* 20. 547-567. 10.1108/17410380910960984.

Baldrige Performance Excellence Program. (2015). 2015-2016 Baldrige Excellence Framework: A Systems Approach to Improving Your Organization's Performance.

Beckford, J. (2002) Quality: A Critical Introduction. USA: Routledge Florence.

Beheshti, H. & Lollar, J. (2003). An empirical study of US SMEs using TQM. *Total Quality Management & Business Excellence.* 14. 839-847. 10.1080/1478336032000090798

Bemowski, K. & Stratton, B. (1995). How do people use the Baldrige award criteria? 28. 43-47.

Bessant, J., Caffyn, S., Gilbert, J., Harding, R. & Webb, S. (1994). Rediscovering continuous improvement. *Technovation,* Vol. 14 No. 1, pp. 17-29.

Bhuiyan, N. & Baghel, A. (2005). An overview of continuous improvement: From the past to the present. *Management Decision.* 43. 761-771. 10.1108/00251740510597761.

Bhuiyan, N. (2011). A Framework for successful new product development. *Journal of Industrial Engineering and Management.* 4. 10.3926/jiem.334.

Boltic, Z., Ruzic, N., Jovanovic, M. & Petrovic, S. (2010). Measuring the performance of quality assurance processes: Pharmaceutical industry deviation management case study. *Accreditation and Quality Assurance.* 15. 629-636. 10.1007/s00769-010-0709-2.

Booz, Allen, & Hamilton. (1982) New Product Management for the 1980's. New York: Booz, Allen & Hamilton, Inc.

Bryman, A. & Bell, E. (2003) Business Research Methods. Oxford University Press, Oxford.

BS 4778. (1987). Quality Vocabulary. British Standards Institute, London, 1987.

Cambridge Dictionaries Online. (2019). Product. URI: https://dictionary.cambridge.org/dictionary/english/product. Cited 2019/10/8.

Carpinetti, L., Buosi, T. & Gerolamo, M. (2003). Quality management and improvement: A framework and a business-process reference model. *Business Process Management Journal.* 9. 543-554. 10.1108/14637150310484553.

Carr, L.P. (1992). Applying cost of quality to a service business. *Sloan Management Reviews*, p.72, Summer.

Carrión-García, A. & Grisales, A. (2015). Quality and sustainability: The deming's chain reaction. *Safety Engineering.* 5. 47-50. 10.7562/SE2015.5.01.07.

Cheah, S., Md Shahbudin, A. & Taib, F. (2011). Tracking hidden quality costs in a manufacturing company: An action research. *International Journal of Quality & Reliability Management.* 28. 405-425. 10.1108/02656711111121816.

Chow, T. W. (1985). Software quality assurance: A practical approach. Silver Spring, MD: IEEE Computer Society Press.

Cooper, R. & Kaplan, R.S. (1988). Measure costs right: Make the right decisions. *Harvard Business Review,* Vol. 66, No. 5, p.96.

Cooper, R. & Kleinschmidt, E. (1994). Determinants of Timeliness in Product Development. *Journal of Product Innovation Management.* 11. 381-396. 10.1016/0737-6782(94)90028-0.

Cooper, R. (1988). The rise of activity-based costing – Part I: What is an activity-based costsystem? *Journal of Cost Management*, Vol.2, No.2, p.45.

Cooper, R. (1990). Stage-Gate Systems: A New Tool for Managing New Products. *Business Horizons.* 33. 44-54. 10.1016/0007-6813(90)90040-I.

Cooper, R. (2000). Doing It Right: Winning with New Products. *IVEY Business Journal.* 64.

Cooper, R. (2008). Perspective: The Stage- Gate® Idea- to- Launch Process—Update, What's New, and NexGen Systems*. *Journal of Product Innovation Management.* 25. 213 - 232. 10.1111/j.1540-5885.2008.00296.x.

Cooper, R., Edgett, S. & Kleinschmidt, E. (1999). New Product Portfolio Management: Practices and Performance. *Journal of Product Innovation Management,* Vol. 16, No. 4, pp. 333-351.

Dahlgaard-Park, S. (2008). Reviewing the European excellence model from a management control view. *The TQM Journal.* 20. 98-119. 10.1108/17542730810857345.

Dean, J.W. & Bowen, D.E. (1994). Management Theory and Total Quality: Improving Research and Practice through Theory Development. *Academy of Management Review,* 19, 392-418.

Deming, W.E. (1986). Out of the Crisis. MIT Press. Cambridge, MA.

Dubey, M. (2016). Developing an Agile Business Excellence Model for Organizational Sustainability. *Global Business and Organizational Excellence.* 35. 60-71. 10.1002/joe.21656.

EFQM. (2012). EFQM, Excellence in Action. Brussels: EFQM.

Feldman, S. (2005). Quality Assurance: Much More than Testing. ACM Queue, February 2005.

Flynn, B. & Saladin, B. (2001). Further Evidence on the Validity of the Theoretical Model Underlying the Baldrige Criteria. *Journal of Operations Management.* 19. 617-652. 10.1016/S0272-6963(01)00072-9.

Flynn, B.B., Schroeder, R.G., & Sakakibara, S. (1994). A Framework for Quality Management Research and an Associated Measurement Instrument. *Journal of Operations Management.* 11. 339-366.

Fonseca, L. (2015). RELATIONSHIP BETWEEN ISO 9001 CERTIFICATION MATURITY AND EFQM BUSINESS EXCELLENCE MODEL RESULTS. *Quality Innovation Prosperity.* 19. 85-102. 10.12776/QIP.V19I1.556.

Ford Motor Company. (1985). Three-Day Statistical Process Control Course Notes. Brentwood, Essex: Ford Motor Company.

Forza, C. & Salvador, F. (2006). Product Information Management for Mass Customization: Connecting Customer, Front-office and Back-office for Fast and Efficient Customization. Palgrave Macmillan, New York. 10.1057/9780230800922.

Galin, D. (2004). Software quality assurance: From theory to implementation. Harlow, UK: Pearson Education Limited.

Gaplin., T. (1997). Making Strategy Work. Jossey-Bass, San Fransisco, CA.

Gebauer, H., Fleisch, E. & Friedli, T. (2005) Overcoming the Service Paradox in Manufacturing Companies. *European Management Journal,* 23, 14-26.

George, M. (2002). Lean Six Sigma: Combining Six Sigma Quality with Lean Production Speed. McGraw-Hill, New York, NY.

Goulden, C. & Rawlins, L. (1995). A hybrid model for process quality costing. *International Journal of Quality & Reliability Management,* Vol.12, No.8, p.32.

H. Kropsu-Vehkapera. (2012). Enhancing understanding of company-wide product data management in ICT companies. Acta Universitatis Ouluensis, Univ. Oulu, Oulu, Finland, 2012. [Online]. Available: http://jultika.oulu.fi/files/isbn9789514297984.pdf

Haines, S. (2009) The Product Manager's Desk Reference. USA: McGraw-Hill Professional.

Hammer, M. (1996). Beyond Reengineering: How the Process – Centered Organization is Changing Our Work and Our Lives. New York, Harper Collins.

Hannila, H., Koskinen, J., Harkonen, J. & Haapasalo, H. (2019). Product-level profitability – Current challenges and preconditions for data-driven, fact-based Product Portfolio Management. *Journal of Enterprise Information Management.* 10.1108/JEIM-05-2019-0127.

Harkonen J., Haapasalo, H. & Hanninen, K. (2015). Productisation: A review and research agenda. *Int. J. Production Economics,* Vol. 164, pp. 65-82.

Harkonen, J., Haapasalo, H. & Hänninen, K. (2015). Productisation: A review and research agenda. *International Journal of Production Economics.* 164. 65–82. 10.1016/j.ijpe.2015.02.024.

Harkonen, J., Tolonen, A. & Haapasalo, H. (2017). Service productisation: systematising and defining an offering. *Journal of Service Management.* 28. 936-971. 10.1108/JOSM-09-2016-0263.

Harkonen, J., Tolonen, A. & Haapasalo, H. (2019). Modelling of Construction Products and Services for Effective Productisation. 13. 335-353. 10.26493/1854-4231.13.335-353.

Hoyle, D. (2017). ISO 9000 Quality Systems Handbook-updated for the ISO 9001: 2015 standard: Increasing the Quality of an Organization's Outputs. 7th ed. Routledge, New York, NY.

Hung, R. (2006). Business Process Management as competitive advantage: A review and empirical study. *Total Quality Management & Business.* 17. 21-40. 10.1080/14783360500249836.

International Organization for Standardization. (2015). Quality management principles. (cited on 3.1.2020). Available: https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100080.pdf

International Organization for Standardization. (2015). Quality management systems - Fundamentals and vocabulary. ISO, Geneva, Switzerland.

Jaafreh, A. (2013). The Effect of Quality Management Practices on Organizational Performance in Jordan: An Empirical Study. *Journal of Financial Research.* 4. 10.5430/ijfr.v4n1p93

Jaakkola, E., Orava, M. & Varjonen, V. (2007). Palvelujen tuotteistamisesta kilpailuetua. Helsinki: Tekes.

Juergensen, T. (2000). Continuous improvement: Mindsets, Capability, Process, Tools and results. The Juergensen Consulting Group, Inc., Indianapolis, IN.

Juran, J.M., Godfrey, A.B. (Eds.) (1998). Juran's Quality Handbook, 5th ed. McGraw-Hill, New York.

JUSE. (2015). The Deming Prize Guide. Union of Japanese Scientists and Engineers. Viewed on December 2019, available:

https://www.juse.or.jp/upload/files/Deming_prize_EN/download/Application_Guide.pdf

Kahn, K. B., Kay, S. E., Slotegraaf, R. J. & Uban, S. (Eds.). (2013). The PDMA Handbook of New Product Development. Hoboken, New Jersey: John Wiley & Sons, Inc.

Kaynak, Hale. (2003). The Relationship Between Total Quality Management Practices and Their Effects on Firm Performance. *Journal of Operations Management.* 21. 10.1016/S0272-6963(03)00004-4.

Kotler, P. & Armstrong, G. (2010). Principles of Marketing. 13th Edition. Upper Saddle River, NJ: Pearson Education Inc.

Krause, D., Beckmann, G., Szech, S., Gebhardt, N., Jonas, H. & Rettberg, R. (2013). Integrated Development of Modular Product Families: A Methods Toolkit. 10.1007/978-1-4614-7937-6_10.

Kropsu-Vehkapera, H. & Haapasalo, H. (2011). Defining Product Data Views for Different Stakeholders. *Journal of Computer Information Systems,* 52, 61-72.

Kropsu-Vehkaperä, H. (2012). Enhancing understanding of company-wide product data management in ICT companies. Acta Universitatis Ouluensis, Univ. Oulu, 2012. [Online]. Available: http://jultika.oulu.fi/files/isbn9789514297984.pdf

Lahtinen, N., Mustonen, E. & Harkonen, J. (2019). Commercial and Technical Productization for Fact-Based Product Portfolio Management Over Lifecycle. *IEEE Transactions on Engineering Management*, In press.

Lakhal, L., Pasin, F. & Limam, M. (2006). Quality management practices and their impact on performance. *International Journal of Quality & Reliability Management*. 23. 625-646. 10.1108/02656710610672461.

Lasrado, F. (2018). Achieving Organizational Excellence: A Quality Management Program for Culturally Diverse Organizations. Springer Nature Switzerland AG. Cham, Switzerland.

Lee, R. & Dale, B. (1998). Business process management: a review and evaluation. *Business Process Management Journal*, Vol. 4 No. 3, pp. 214-225.

Lee, S. & Ahn, H. (2008). Assessment of process improvement from organizational change. *Information & Management*. 45. 270-280. 10.1016/j.im.2003.12.016.

Linderman, K., Schroeder, R., Zaheer, S. & Choo, A. (2003). Six sigma: a goal – theoretic perspective. *Journal of Operations Management*, Vol. 21 No. 2, pp. 193-203.

Manz, C.C., Stewart, G.L. (1997). Attaining flexible stability by integrating total quality management and socio-technical systems theory. *Organization Science 8* (1), 59-70.

Marsh, J. (1989). Process modeling for quality improvement. *Proceedings of the Second International Conference on Total Quality Management*, p.111.

McCall, J., Richards, P. & Walters, G. (1977). Factors in Software Quality, Vols 1-3.

Modarres, B. & Ansari, A. (1987). Two new dimensions in the cost of quality. *International Journal of Quality & Reliability Management*, Vol.4, No.4, p.9.

Molina, L., & Lloréns-Montes, J. & Ruiz-Moreno, A. (2007). Relationship Between Quality Management Practices and Knowledge Transfer. *Journal of Operations Management.* 25. 682-701. 10.1016/j.jom.2006.04.007.

Montgomery, D.C. (2009) Introduction to Statistical Quality Control. 6th Edition, John Wiley & Sons, New York.

Murugesan, S. (1994). Attitude towards testing: A key contributor to software quality. *IEEE's Proceedings of 1st International Conference on Software Testing, Reliability and Quality Assurance.*

Niven, P. (2002). Balanced Scorecard Step by Step: Maximizing Performance and Maximizing Results. John Wiley & Sons, New York, NY.

Oakland, J.S. (2014). Total quality management and operational excellence: Text with cases. 10.4324/9781315815725.

Owens, D. & Khazanchi, D. (2009). Software Quality Assurance. *Handbook of Research on Technology Project Management, Planning, and Operations,* pp. 242-263. Information Science Publishing.

Pardeep, G. (2013). Total Quality Management & Just In Time. *Indus World School Of Business*

Porter, L.J. & Rayner, P. (1992). Quality Costing for Total Quality Management. *International Journal of Production Economics*, 27, 69-81.

Pressman, R. S. (2000). Software Engineering – A Practitioner's Approach, European adaptation by D. Ince, 5th edn. Ch. 19, McGraw-Hill International, London.

Priede, J. (2012). Implementation of Quality Management System ISO 9001 in the World and Its Strategic Necessity. *Procedia - Social and Behavioral Sciences.* 58. 1466-1475. 10.1016/j.sbspro.2012.09.1133.

Rasmusson, D. (2006). The SIPOC picture book: a visual guide to the SIPOC/DMAIC relationship. Oriel Incorporated, Madison, WI.

Rissanen, T. (2002), Projektilla tulokseen. Pohjantähti, Jyväskylä.

Robinson, A. (1990). Modern Approaches to Manufacturing Improvement. Productivity Press, Portland, OR.

Saaskvuori, A., & Immonen, A. (2008). Product Life-Cycle Management, 3rd ed. Berlin, Germany: Springer.

Salvador, F. (2007). Toward a Product System Modularity Construct: Literature Review and Reconceptualization. *Engineering Management, IEEE Transactions* on. 54. 219 - 240. 10.1109/TEM.2007.893996.

Samuelsson, P. & Nilsson, L. (2002). Self-assessment practices in large organisations: Experiences from using the EFQM excellence model. *International Journal of Quality & Reliability Management*. 19. 10-23. 10.1108/02656710210413426.

Sandoval-Chavez, D.A. & Beruvides, M.G. (1998). Using Opportunity Costs to Determine the Cost of Quality: A Case Study in a Continuous-Process Industry. *Engineering Economist.* 43, 107-124.

Schiffauerova, A. & Thomson, V. (2006). A review of research on cost of quality models and best practices. *International Journal of Quality & Reliability Management.* 23. 10.1108/02656710610672470.

Schilling, M. & Hill, C. (1998). Managing the New Product Development Process. *Academy of Management Executive*. 12. 67-81. 10.5465/AME.1998.1109051.

Schroeder, D., Robinson, A. (1991). America's most successful export to Japan: continuous improvement programs. *Sloan Management Review*, Vol. 32 No. 3, pp. 67-81.

Schulmeyer, G. (2007). Handbook of Software Quality Assurance. Fourth ed. Artech House Publishers. Massachusetts, USA.

Silvola, R., Tolonen, A., Harkonen, J., Haapasalo, H. & Mannisto, T. (2019). Defining one product data for a product. *International Journal of Business Information Systems.* 30. 489. 10.1504/IJBIS.2019.099308.

Sipilä, J. (1996). Asiantuntijapalveluiden tuotteistaminen. Porvoo: WSOY.

Slaughter, S.A., Harter, D.E. & Krishnan, M.S. (1998). Evaluating the cost of software quality. *Communications of the ACM*, Vol.41, p.67.

Tian, J. (2005). Software Quality Engineering: Testing, Quality Assurance, and Quantifiable Improvement. John Wiley & Sons.

Tolonen, A. (2016). Product portfolio management over horizontal and vertical portfolios. Acta Universitatis Ouluensis, Univ. Oulu, 2016. [Online]. Available: http://jultika.oulu.fi/files/isbn9789526212678.pdf

Tolonen, A., Harkonen, J. & Haapasalo, H. (2014). Product Portfolio Management - Governance For Commercial and Technical Portfolios Over Life Cycle. *Technology and Investment.* 5. 173-183. 10.4236/ti.2014.54016.

Tolonen, A., Shahmarichatqhieh, M., Härkönen, J. & Haapasalo, H. (2015). Product Portfolio Management - Targets and Key Performance Indicators for Product Portfolio Renewal over Life Cycle. *International Journal of Production Economics.* 170. 468-477. 10.1016/j.ijpe.2015.05.034.

Trott, P. (2008). Innovation Management and New Product Development, Pearson Education Limited, Harlow.

Tsai, W.H. (1998). Quality cost measurement under activity-based costing. *International Journal of Quality and Reliability Management*, Vol.15, No.6, p.719.

Tsiotras, G. & Gotzamani, K. (1996). ISO 9000 as an entry key to TQM: the case of Greek industry. *International Journal of Quality & Reliability Management,* Vol. 13 No. 4, pp. 64-76. https://doi.org/10.1108/02656719610114407.

Tummala, V. & Tang, C.L. (1996). Strategic quality management, Malcolm Baldrige and European quality awards and ISO 9000 certification. *International Journal of Quality & Reliability Management.* 13. 8-38. 10.1108/02656719610114371.

Ulrich, K. T., & Eppinger, S. D. (2012). Product Design and Development (5th ed.). New York, NY: McGraw-Hill Irwin.

Ulrich, K.T. & Eppinger, S.D. (2008) Product Design and Development (4th ed.). McGraw-Hill, New York.

Venters, C., Lau, L., Griffiths, M., Holmes, V., Ward, R., Jay, C., Dibsdale, C. & Xu, J. (2014). The Blind Men and the Elephant: Towards an Empirical Evaluation Framework for Software Sustainability. *Journal of Open Research Software.* 2. 10.5334/jors.ao.

Vivek, N. (2005). Quality management system handbook for product development companies. CRC Press, Boca Raton, FL.

Wang, R. Y., Storey, V. C. & Firth, C. P. (1995). A framework for analysis of data quality research. *IEEE transactions on knowledge and data engineering,* Vol. 7 No. 4, pp. 623-640.

Wiele, T., Iwaarden, J., Williams, R. & Dale, B. (2005). Perceptions about the ISO 9000 (2000) quality system standard revision and its value: The Dutch experience. *International Journal of Quality & Reliability Management.* 22. 10.1108/02656710510577189.

Woodhouse, D. (2003). Quality Improvement through Quality Audit. *Quality in Higher Education.* 9. 133-139. 10.1080/13538320308156.

Yang, J., Dale, B. & Siow, C. (2001). Self-assessment of excellence: An application of the evidential reasoning approach. *International Journal of Production Research.* 39. 3789-3812. 10.1080/00207540110069078.

Yin, R.K. (2009). Case study research: Design and methods (4th Ed.). Thousand Oaks, CA: Sage.

Youssef, M. & Zairi, M. (2009). Quality Function Deployment: A Main Pillar for Successful Total Quality Management and Product Development. *International Journal of Quality & Reliability Management,* Vol. 12, No. 6, pp. 9-23. MCB University Press Ltd. West Yorkshire, UK.

APPENDICES

Appendix 1: Internal questionnaire (productization)

1. Products and product structure

1.1 What is a product from your organization's point of view?
1.2 To what kind of product families do you divide your products?
1.3 How many separate products or product configurations exist? Is there too many or too few products?
1.4 How large are product specific volumes?
1.5 Are all products in the product catalogue?
1.6 What is a typical life cycle for a 9Solutions product?
1.7 Are commercial and technical product portfolios defined?
1.8 Do you separate the product that customer sees and everything else related to the product (installation, maintenance)?
1.9 Do you sell product assemblies or individual products?
1.10 How and when are the sold assemblies and sub-assemblies defined?

2. Productization

2.1 What are currently the biggest challenges regarding commercial and technical productization?
2.2 Which factors have an influence on the number of sales items?
2.3 Does the product include hardware, software and service aspects?
2.4 How products are added/removed?
2.5 Are there modular elements in products?
2.6 Do the products share common parts?
2.7 How repeatability is utilized in the products?
2.8 How does the development of product variants differ from the development of a whole new product?
2.9 How are quality and testing activities included in the product development process?

Appendix 2: Internal questionnaire (quality)

1. Interview questions, background:

1.1 What is your role in the company?
1.2 What is your work experience in the company?

2. Quality management issues in the company:

2.1 What does quality mean to you?
2.2 What does quality mean in your own team?
2.4 How do you view the current state of product quality in the company?
2.5 Are you aware of quality systems in use (ISO 9001 etc.) in the company?
2.6 How does (the lack of) quality impact the company's results?
2.7 What product quality related data is created or collected in your work? How often is that data used?
2.8 Are the suppliers certified and qualified for quality?
2.9 What are the current challenges in managing product quality at 9Solutions?
2.10 How would you improve the overall quality of products?
2.11 Name an example of 9Solutions product with good quality. Product with bad quality?

3. Examining existing performance:

3.1 Quality control and inspection related questions:

3.1.1 What are the main tools for finding faulty products?
3.1.2 What inspection activities are used in the quality control?
3.1.3 Is there a quality manual in the company?
3.1.4 How product related documents are controlled?
3.1.5 How are defects and customer returns handled?
3.1.6 How is product quality measured? Key performance indicators?
3.1.7 What is the current state of quality planning?

3.1.8 When faulty products are detected?

3.1.9 How products are tested? Are the current testing methods enough?

3.2 Quality assurance related questions:

3.2.1 Is the quality system documented? How?

3.2.2 Can the origin of faulty features be identified?

3.2.3 Is there a tracing and tracking system of products or product batches?

3.2.4 Are there statistical methods in use to manage quality?

3.2.5 Are quality costs calculated?

3.3 Total quality management related questions:

3.3.1 How are the senior managers promoting a culture of excellence in the organization?

3.3.2 Is there a clear long-term strategy for quality management in the organization?

3.3.5 Does your organization provide training to people working on quality-related activities? Have people been trained in how to prevent errors and problems?

3.3.6 How does the management share information with employees, listen to them and act on their suggestions?

3.3.7 What issues exist regarding internal and external communication within the organization?

3.3.8 Is teamwork practiced in the organization? In what forms?

3.3.9 Is there defined internal and external key performance indicators to measure improvement (i.e. business measures, competitive, benchmarking, customer surveys)?

3.3.10 What is corporate quality culture like? Does the culture promote continuous improvement to everyone?

3.3.12 Does established quality objectives and responsibilities exist for different functions and levels of the organization?

3.3.13 Are activities oriented to focus on the customer needs? How does customer needs effect on defining requirements for the organization and its products?

3.4 What quality management areas were not present in this interview? Proposals for this interview?

3.5 Estimate on a scale 1-5:

3.5.1 "How important is that 9Solutions improves its quality management?"
1 = Not important, 2 = Somewhat important, 3 = Important, 4 = Very important, 5 = It's the most important thing

3.5.2 "How would you rate the quality level of 9Solutions products and solutions?"
1 = Very Poor, 2 = Poor, 3 = Adequate, 4 = Good, 5 = Excellent

3.5.3 "How proud are you of the quality of 9Solutions products and solutions?"
1 = Not Proud, 2 = Somewhat Proud, 3 = Basic Quality level, 4 = Proud, high quality 5 = Proud, we have the best quality

3.5.4 "Select the most suitable statement which describes your daily work"
1: Customer experience is not important in my daily work at 9Solutions
2: Customer experience is somewhat important in my daily work at 9Solutions
3: Customer experience is important in my daily work at 9Solutions
4: Customer experience is very important in my daily work at 9Solutions
5: Customer experience is the most important topic in my daily work at 9Solutions

3.5.5 "Senior management is committed to high product quality by promoting quality culture for 9Solutions"
1 = Not at all, 2 = Somewhat committed, 3 = Commited, 4 = Very committed, 5 = It's the most important topic for senior management

3.5.6 "Would you recommend 9Solutions products and solutions to your friend or family member?"
Scale from 1 to 10 (NPS): 1 2 3 4 5 6 7 8 9 10

4. Requirements for quality management system

4.1 Are company's quality policies defined and published?
4.2 How does the management review the quality system and previously decided actions? How often?

4.3 Are quality records created internally? From the suppliers?

4.4 What tools are used in product design and development to ensure that the output meets the requirements

4.5 How suppliers are evaluated and selected?

4.6 How product and service delivery processes are controlled?

4.7 How care and support services are planned?

4.11 How is collected data analyzed?

4.12 How causes of nonconformity are eliminated?

Appendix 3. Benchmarking questionnaire

1. Quality and QM

1.1 What does quality mean for your company?
1.2 How do you view the current state of product quality in the company? What is the significance of quality for business?
1.3 What type of quality management system do you have in use? Certifications?
1.4 How is quality managed daily in the company?
1.5 How does the company ensure good customer experience with limited resources?
1.6 How does the company invest in quality? How are resources allocated to quality, for example in terms of human resources?
1.7 What kind of quality related challenges have existed in the company in the past? How product quality has been approached?
1.8 How the quality management system is maintained and previously decided actions are reviewed in the company? How often?
1.9 How has quality management developed with the company's growth/development?
1.10 How would you improve current the quality management system or quality culture in the company?

2. Measuring quality and performance

2.1 What quality and customer experience related metrics are used in the company?
2.2 How are costs of quality measured in the company?
2.3 What quality targets have been developed in the company?
2.4 How does the company keep track on achieving quality goals?
2.5 How and when is the testability and test coverage of a product defined?

3. Quality in PD

3.1 How quality issues are considered in product development and specifically in software development? Is there a specific development model for software development?
3.2 How product development projects and related roles, responsibilities and phases

have been organized in the company?

3.3 Is there a gate model in use for product development? (or another model)

3.4 How and when are the product development projects reviewed during the project?

3.5 To what extent is the product development process documented?

3.6 What is the role of the customer in product development? To what extent does the customer participate in new product development?

Appendix 4: Benchmarking summary

	Company A	Company B	Company C
Quality management			
QMS characteristics	-The whole organization participates in continuous improvement -Striving for sufficient quality level -Precise quality targets in operations	-The organization must fulfil the set requirements -Clear requirements and targets for different functions and departments of the organization -QMS focuses on quality through the whole organization and different departments	-Quality is recognized as one of the main functions of the company -Defined key processes for all organizational functions -Set metrics for almost all processes -Quality manual contains processes, metrics, work instructions, audits
QMS and certification	ISO 9001:2015	ISO 9001:2015, ISO 14001, 5S practices	ISO 9001:2015
Daily quality activities	-Memo practice for employees -Continuous filling of memos by the employees	-Specified KPIs for every organizational function -KPIs are reviewed monthly	-Reviewing KPIs and related metrics -Internal audits
Ensuring customer satisfaction	-Customer feedback memo -Reviewed every two weeks	-Focusing on essential issues and to be as efficient as possible -Prioritization of big customers and critical issues	-Investing in customer support and service -Big customers get the most attention
Investing in quality	-A few persons with quality title -Quality is budgeted beside other projects -regular QMS auditing and consulting	-One quality manager and few persons with quality title -Every employee has been trained for ISO 9001	-One quality manager -Investing in customer support and service -Maintain of quality manual -Designated responsibilities for processes and metrics
Quality related challenges	-Updating QMS to correspond to the newest standard -Internal random test auditing if a problem has been detected	-Quality variation in small product batches	-People not following processes and instructions
QMS maintenance	-Cumulative quality memo	-Action list, which includes improvements, targets and KPIs -The list is monitored monthly and annually on audits -The list is open for everyone in the	-Internal audits -Audit annually for every main function -“Annual wheel of quality”: defined internal audits for every function -“Internal audit plan” includes schedule and

		organization -Quality manager lists the emerged issues, that are reviewed together	checklists for audits -Actions are based on measurable facts, not opinions
QMS evolution	-From heavy QM software to light memo system	-Implementing QMS -KPIs and action lists have been introduced with the QMS -Processes in product development have become more precise and better monitored -More checklists, records of audits -More systematic way of accepting things	-From process-oriented system to checklist-oriented system -Some processes have been combined -New processes identified, such as product ramp-down process
Quality measures			
Quality metrics	-Customer feedback -Customer complaints -Maintenance work	-KPIs: reliability of delivery, production yield, capacity, customer claims, maintenance work, customer returns, most common faults -Staying on schedule in PD	-KPIs for different functions -Customer interviews by subcontract company -Customers can set metrics themselves
Cost of Quality measurement	-Quality as cost centre -Quality is project among others	-Maintenance costs	-Product replacement costs
Quality targets	-Improving procedures -Satisfied customers -Continuous improvement of know-how	-Used metrics originate from set targets -On-time delivery -Customer satisfaction -Human resource metrics -Employee well-being -Different departments collect their own metrics and report the results to quality manager	-Quality metrics -Set maximum count for customer claims and product replacement -Ensuring customer satisfaction is the ultimate quality target
Reviewing quality targets		-KPIs are reviewed monthly and annually in audits	-Reviewing metrics as they are defined in the quality manual
Testing	-Acceptance Test Procedure (ATP) document -Testing is planned in the beginning of product development	-Test requirements are defined with product specifications -Testing and related yield are reviewed before moving to mass production -Out-of-box audit	-Test planning takes place in the beginning of product development
Quality in PD			

Product development model to achieve quality products	Evaluating suppliers → estimating risks → planning → authentication → acceptance audit → accepting for production	-Similar development processes throughout the different departments -Agile-like model	-The product development process is defined, including related sub-processes -Waterfall resembling model for software development
Roles and responsibilities	-Designated responsibilities -Designated process owners -Project manager leads the development project forward and leading it to production	-Line organizations according to organizational functions -Responsibilities are set with specified job titles -Processes determine some of the responsibilities -Project manager leads the NPD project -Program manager on top level → product development manager and R&D manager → head designers	-A project manager for every product development project -In the beginning of the project, involved persons are defined, based on the nature of the project -If there is no required person in the company, a subcontractor is used
PD operational model	-Iterative prototyping -Git in software development -Customer involvement	-Milestones 1-6 -Every milestone includes a checklist -Process chart for every milestone -Milestones include sub-milestones for different functions -Sub-milestones are composed to program milestone	-"Guide for project activity" includes basic information of the project -Project described in process form: defining requirements, preliminary investigation, technical specifications, audits -Three top level milestones for product development projects, 14 in total -Project manager assembles the milestone audits, manages the transcript and is responsible for managing changes and re-audits
Reviewing product development projects	-Developer arranges the reviews -Firmware modification review -Firmware acceptance tests, related to ATP document	-Linked evidence on completed checklist points -Deficiencies are listed as actions and reviewed on next milestone meeting	-Three top level milestones -14 milestones in total -Project manager arranges the milestone audits
Documentation of product development process	-Core processes → detailed descriptions -A one page manifest when software is end of its life - includes who has	-Process charts, on company and function levels -Processes are described in quality manual	-Process flowchart includes the required minimum steps regarding all product development projects

	made it, to whom it was made	-Milestone checklists include outputs of process steps	
Customer involvement in product development	-Contract review document describes what has been agreed with the customer (marketing dep.) -Active in the beginning of PD -Customer tests the finished product → iterative method	-Customer may state product demands or testing demands -Big customers validate the product by themselves or demand specific test reports -Feedback from old customers regarding the earlier versions of product is reviewed	-Goal: all product development projects begin from a customer need -Some customers pay for the whole product development project and are involved in audits -Opportunity evaluation/qualification for other projects: conversations with customers to evaluate the reality of the customer need -Released products are tested by customers, to make changes before mass production